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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 930

[Doc. No. AMS–FV–14–0077; FV14–930–2 FR]

Tart Cherries Grown in the States of Michigan, et al.; Free and Restricted Percentages for the 2014–15 Crop Year for Tart Cherries

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule implements a recommendation from the Cherry Industry Administrative Board (Board) to establish free and restricted percentages for the 2014–15 crop year under the marketing order for tart cherries grown in the states of Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin (order). The Board locally administers the marketing order and is comprised of producers and handlers of tart cherries operating within the production area. This action establishes the proportion of tart cherries from the 2014 crop which may be handled in commercial outlets at 80 percent free and 20 percent restricted. In addition, this action increases the carry-out volume of fruit to 50 million pounds for this season. These percentages should stabilize marketing conditions by adjusting supply to meet market demand and help improve grower returns.

DATES: Effective June 2, 2015.

FOR FURTHER INFORMATION CONTACT: Jennie M. Varela, Marketing Specialist, or Christian D. Nissen, Regional Director, Southeast Marketing Field Office, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA; Telephone: (863) 324–3375, Fax: (863) 291–8614, or Email: *Jennie.Varela@ams.usda.gov* or *Christian.Nissen@ams.usda.gov.*

Small businesses may request information on complying with this regulation by contacting Jeffrey Smutny, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Jeffrey.Smutney@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This final rule is issued under Marketing Agreement and Order No. 930, both as amended (7 CFR part 930), regulating the handling of tart cherries produced in the States of Michigan, New York, Pennsylvania, Oregon, Utah, Washington and Wisconsin, hereinafter referred to as the ''order.'' The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

The Department of Agriculture (USDA) is issuing this proposed rule in conformance with Executive Orders 12866, 13563, and 13175.

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the order provisions now in effect, free and restricted percentages may be established for tart cherries handled during the crop year. This rule establishes free and restricted percentages for tart cherries for the 2014–15 crop year, beginning July 1, 2014, through June 30, 2015.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This final rule establishes free and restricted percentages for the 2014–15 crop year at 80 percent free and 20 percent restricted. In addition, this action increases the carry-out volume of fruit to 50 million pounds for calculation purposes for this season. This action should stabilize marketing conditions by adjusting supply to meet market demand and help improve grower returns. The change in carry-out was recommended by the Board at a meeting on June 26, 2014, and the final percentages were recommended by the Board at a meeting on September 11, 2014.

Section 930.51(a) of the order provides authority to regulate volume by designating free and restricted percentages for any tart cherries acquired by handlers in a given crop year. Section 930.50 prescribes procedures for computing an optimum supply based on sales history and for calculating these free and restricted percentages. Free percentage volume may be shipped to any market, while restricted percentage volume must be held by handlers in a primary or secondary reserve, or be diverted or used for exempt purposes as prescribed in §§ 930.159 and 930.162 of the regulations. These activities include, in part, the development of new products, sales into new markets, the development of export markets, and charitable contributions.

Under § 930.52, only those districts with an annual average production of at least six million pounds are subject to regulation, and any district producing a crop which is less than 50 percent of its annual average is exempt. The regulated districts for the 2014–2015 crop year are: District 1—Northern Michigan; District 2—Central Michigan; District 3—Southern Michigan; District 4—New York; District 7—Utah; District 8—Washington; and District 9—Wisconsin. Districts 5 and 6 (Oregon and Pennsylvania, respectively) are not regulated for the 2014–15 season.

Demand for tart cherries and tart cherry products tends to be relatively stable from year to year. Conversely, annual tart cherry production can vary greatly. In addition, tart cherries are processed and can be stored and carried over from crop year to crop year, further impacting supply. As a result, supply and demand for tart cherries are rarely in balance.

Because demand for tart cherries is inelastic, total sales volume is not very responsive to changes in price. However, prices are very sensitive to changes in supply. As such, an oversupply of cherries would have a sharp negative effect on prices, driving down grower returns. The Board, aware of this economic relationship, focuses on using the volume control provisions in the order to balance supply and demand to stabilize industry returns.

Pursuant to § 930.50 of the order, the Board meets on or about July 1 to review sales data, inventory data, current crop forecasts, and market conditions for the upcoming season and, if necessary, to recommend preliminary free and restricted percentages if anticipated supply would exceed demand. After harvest is complete, but no later than September 15, the Board meets again to update their calculations using actual production data, consider any necessary adjustments to the preliminary percentages, and determine if final free and restricted percentages should be recommended to the Secretary.

The Board uses sales history, inventory, and production data to determine whether there is a surplus, and if so, how much volume should be restricted to maintain optimum supply. The optimum supply represents the desirable volume of tart cherries that should be available for sale in the coming crop year. Optimum supply is defined as the average free sales of the prior three years plus desirable carry-out inventory. Desirable carry-out is the amount of fruit needed by the industry to be carried into the succeeding crop year to meet marketing demand until the new crop is available. Desirable carry-out is set by the Board after considering market circumstances and needs. Section 930.50(a) specifies that desirable carry-out can range from zero to a maximum of 20 million pounds, but also authorizes the Board to establish an alternative carry-out figure with the approval of the Secretary.

After the Board determines optimum supply and desirable carry-out, it must examine the current year's available volume to determine whether there is an oversupply situation. Available volume includes carry–in inventory (any inventory available at the beginning of the season) along with that season's production. If production is greater than the optimum supply minus carry-in, the difference is considered surplus. This surplus tonnage is divided by the sum of production in the regulated districts to reach a restricted percentage. This percentage must be held in reserve or used for approved diversion activities, such as exports.

The Board met on June 26, 2014, and computed an optimum supply of 218 million pounds for the 2014–15 crop year using the average of free sales for the three previous seasons and a desirable carry-out of 20 million pounds. The Board then subtracted the estimated carry-in of 81 million pounds from the optimum supply to calculate the production needed from the 2014–15 crop to meet optimum supply. This number, 137 million pounds, was subtracted from USDA's estimated 2014–15 production of 264 million pounds to calculate a surplus of 127 million pounds of tart cherries. The surplus minus the market growth factor was then divided by the expected production in the regulated districts (261 million pounds) to reach a preliminary restricted percentage of 41 percent for the 2014–15 crop year.

In discussing the calculations, industry participants commented that a carry-out of 20 million pounds would not meet their needs at the end of the season before the new crop is available. To address that concern, the Board recommended increasing the desirable carry-out to 50 million pounds for the 2014–2015 season. This change increased the optimum supply to 248 million pounds, reducing the surplus to 97 million pounds.

The Board also discussed whether the three-year average was an accurate estimate of supply needed for the coming season, considering the substantial loss of supply in 2012 due to weather. Including the use of reserves, sales in 2012–13 reached only 123 million pounds, nearly 100 million pounds less than 2013–14 sales. Using data from earlier seasons, the Board agreed that 250 million pounds of free supply is needed in a typical season and voted to make an economic adjustment of 52 million pounds to reach that level.

In addition, USDA's ''Guidelines for Fruit, Vegetable, and Specialty Crop Marketing Orders'' specify that 110 percent of recent years' sales should be made available to primary markets each season before recommendations for volume regulation are approved. This requirement is codified in § 930.50(g) of the order, which specifies that in years when restricted percentages are established, the Board shall make available tonnage equivalent to an additional 10 percent of the average sales of the prior three years for market expansion (market growth factor). The Board complied with this requirement by adding 20 million pounds (198 million times 10 percent, rounded) to the free supply.

The economic adjustment and market growth factor further reduced the preliminary surplus to 25 million pounds. After these adjustments, the preliminary restricted percentage was recalculated as 10 percent (25 million pounds divided by 261 million pounds).

The Board met again on September 11, 2014, to consider establishing final volume regulation percentages for the 2014–15 season. The final percentages are based on the Board's reported production figures and the supply and demand information available in September. The total production for the 2014–15 season was 297.7 million pounds, 34 million pounds above USDA's June estimate. In addition, growers diverted 0.2 million pounds in the orchard, leaving 297.5 million pounds available to market. Using the actual production numbers, and accounting for the recommended increase in desirable carry-out and economic adjustment, as well as the market growth factor, the restricted percentage was recalculated.

The Board subtracted the carry-in figure used in June of 81 million pounds from the optimum supply of 248 million pounds to determine 167 million pounds of 2014–15 production would be necessary to reach optimum supply. The Board subtracted the 167 million pounds from the actual production of 298 million pounds, resulting in a surplus of 131 million pounds of tart cherries. The surplus was then reduced by subtracting the economic adjustment of 52 million pounds and the market growth factor of 20 million pounds, resulting in an adjusted surplus of 59 million pounds. The Board then divided this final surplus by the actual production in the regulated districts (295 million pounds) to calculate a restricted percentage of 20 percent with a corresponding free percentage of 80 percent for the 2014–15 crop year, as outlined in the following table:

	Millions of pounds
Final Calculations:	
(1) Average sales of the prior three years	198
(2) Plus desirable carry-out	50
(3) Optimum supply calculated by the Board	248
(4) Carry-in as of July 1, 2014	81
(5) Adjusted optimum supply (item 3 minus item 4)	167
(6) Board reported production	298
(7) Surplus (item 6 minus item 5)	131
(8) Total economic adjustments	52
(9) Market growth factor	20
(10) Adjusted Surplus (item 7 minus items 8 and 9)	59
(11) Crop estimate for regulated districts	295
	Percent
Final Percentages:	
Restricted (item 10 divided by item 11 × 100)	20
Free (100 minus restricted percentage)	80

The primary purpose of setting restricted percentages is an attempt to bring supply and demand into balance. If the primary market is oversupplied with cherries, grower prices decline substantially. Restricted percentages have benefited grower returns and helped stabilize the market as compared to those seasons prior to the implementation of the order. The Board believes the available information indicates that a restricted percentage should be established for the 2014–15 crop year to avoid oversupplying the market with tart cherries. Consequently, based on its discussion of this issue and the result of the above calculations, the Board recommended final percentages of 80 percent free and 20 percent restricted by a vote of 16 in favor and 2 against.

Of the two Board members who opposed the recommendation, one stated that the industry should focus on sales rather than restriction and the other expressed concerns that some segments would be more impacted by the restriction than others.

Regarding maximizing sales, one member noted that even storm-damaged fruit had been bought for processing, signaling that the processors still needed fruit toward the end of harvest. Other members, however, noted the extra sales some farmers experienced may have simply been due to gaps left by the areas that had damage, which reduced the amount of fruit available to fully supply their processors. Additionally, the economic adjustment and market growth factor included in the recommended restriction make additional fruit available for sales.

A member also noted that some processors, such as those making pie filling, are not likely to purchase excess fruit and would have to restrict their sales. Another believed this level of restriction would signal to the ingredient market that processed fruit may be hard to obtain. However, others stated that a preliminary restriction was announced before harvest and all processors, regardless of product segment, are familiar with the process. Also, though the restricted percentage increased since the preliminary announcement in June, the total volume of fruit available to the market remained unchanged.

Finally, there were also some comments regarding incorporating sales of imported fruit into the demand considerations and that rigid interpretation of the supply formula does not allow the Board to react to the current market conditions. As the order does not provide for reporting processing of imported fruit or regulating such fruit, there are no reliable data on the issue. Others noted that with the increased recommended carry-out, the market growth factor, and adjustment to the demand calculations, the Board has taken steps toward making enough fruit available to continue current growth and have fruit in reserve in case of another crop disaster.

After reviewing the available data, and considering the concerns expressed, the Board determined that a 20 percent restriction with a carry-out volume of 50 million pounds meets sales needs and establishes some reserves without oversupplying the market. Thus, the Board recommended establishing final percentages of 80 percent free and 20 percent restricted.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 600 producers of tart cherries in the regulated area and approximately 40 handlers of tart cherries who are subject to regulation under the order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts of less than $750,000 and small agricultural service firms have been defined as those having annual receipts of less than $7,000,000 (13 CFR 121.201).

According to the National Agricultural Statistics Service (NASS) and Board data, the average annual grower price for tart cherries during the 2013–14 season was $0.35 per pound, and total shipments were around 289 million pounds. Therefore, average receipts for tart cherry producers were around $168,800, well below the SBA threshold for small producers. In 2014, The Food Institute estimated an f.o.b. price of $0.96 per pound for frozen tart cherries, which make up the majority of processed tart cherries. Using this data, average annual handler receipts were about $6.9 million, which is also below the SBA threshold for small agricultural service firms. Assuming a normal

distribution, the majority of producers and handlers of tart cherries may be classified as small entities.

The tart cherry industry in the United States is characterized by wide annual fluctuations in production. According to NASS, tart cherry production in 2011 was 232 million pounds, 85 million pounds in 2012, and in 2013, production was 294 million pounds. Because of these fluctuations, the supply and demand for tart cherries are rarely equal.

Demand for tart cherries is inelastic, meaning changes in price have a minimal effect on total sales volume. However, prices are very sensitive to changes in supply, and grower prices vary widely in response to the large swings in annual supply, with prices ranging from a low of 7.3 cents in 1987 to a high of 46.4 cents in 1991.

Because of this relationship between supply and price, oversupplying the market with tart cherries would have a sharp negative effect on prices, driving down grower returns. The Board, aware of this economic relationship, focuses on using the volume control authority in the order in an effort to balance supply and demand in order to stabilize industry returns. This authority allows the industry to set free and restricted percentages as a way to bring supply and demand into balance. Free percentage cherries can be marketed by handlers to any outlet, while restricted percentage volume must be held by handlers in reserve, diverted, or used for exempted purposes.

This final rule establishes free and restricted percentages using an increased carry-out volume of 50 million pounds for the 2014–15 crop year under the order for tart cherries. This action controls the supply of tart cherries by establishing percentages of 80 percent free and 20 percent restricted for the 2014–15 crop year. These percentages should stabilize marketing conditions by adjusting supply to meet market demand and help improve grower returns. This rule regulates tart cherries handled in Michigan, New York, Utah, Washington, and Wisconsin. The authority for this action is provided for in §§ 930.51(a) and 930.52 of the order. The Board recommended this action at a meeting on September 11, 2014.

This action will result in some fruit being diverted from the primary domestic markets. However, as mentioned earlier, the USDA's ''Guidelines for Fruit, Vegetable, and Specialty Crop Marketing Orders'' specify that 110 percent of recent years' sales be made available to primary markets each season before recommendations for volume regulation are approved. The quantity available under this rule is greater than 110 percent of the quantity shipped in the prior three years.

In addition, there are secondary uses available for restricted fruit, including the development of new products, sales into new markets, the development of export markets, and being placed in reserve. While these alternatives may provide different levels of return than the sales to primary markets, they play an important role for the industry. The areas of new products, new markets, and the development of export markets utilize restricted fruit to develop and expand the markets for tart cherries. In 2011–12, the last season there was a restriction, these activities accounted for more 39 million pounds in sales, 14 million of which were exports.

Placing tart cherries into reserves is also a key part of balancing supply and demand. Although the industry must bear the handling and storage costs for fruit in reserve, reserves stored in large crop years are used to supplement supplies in short crop years. The reserves allow the industry to mitigate the impact of oversupply in large crop years, while allowing the industry to maintain and supply markets in years where production falls below demand. Further, storage and handling costs are more than offset by the increase in price when moving from a large crop to a short crop year.

In addition, the Board recommended an increased carry-out of 50 million pounds and made a demand adjustment of 52 million pounds in order to make the regulation less restrictive. Even with the recommended restriction, over 300 million pounds of fruit will be available to the domestic market. Consequently, it is not anticipated that this action will unduly burden growers or handlers.

While this action could result in some additional costs to the industry, these costs are more than outweighed by the benefits. The purpose of setting restricted percentages is to attempt to bring supply and demand into balance. If the primary market (domestic) is oversupplied with cherries, grower prices decline substantially. Without volume control, the primary market would likely be oversupplied, resulting in lower grower prices.

The three districts in Michigan, along with the districts in New York, Utah, Washington, and Wisconsin, are the restricted areas for this crop year with a combined total production of 295 million pounds. A 20 percent restriction means 236 million pounds will be available to be shipped to primary markets from these five states. The 236 million pounds from the restricted districts, nearly 3 million pounds from the unrestricted districts (Oregon and Pennsylvania), and the 81 million pound carry-in inventory make a total of 320 million pounds available as free tonnage for the primary markets. In comparison, the 12 percent restriction in 2011–2012 made less than 262 million pounds available.

Prior to the implementation of the order, grower price often did not come close to covering the cost of production. The most recent costs of production determined by representatives of Michigan State University are an estimated $0.33 per pound. To assess the impact that volume control has on the prices growers receive for their product, an econometric model has been developed. Based on the model, the use of volume control should have a positive impact on grower returns for this crop year. With volume control, grower prices are estimated to be approximately $0.03 per pound higher than without restrictions.

In addition, absent volume control, the industry could start to build large amounts of unwanted inventories. These inventories would have a depressing effect on grower prices. The econometric model shows for every 1 million-pound increase in carry-in inventories, a decrease in grower prices of $0.0037 per pound occurs.

Retail demand is assumed to be highly inelastic, which indicates that changes in price do not result in significant changes in the quantity demanded. Consumer prices largely do not reflect fluctuations in cherry supplies. Therefore, this action should have little or no effect on consumer prices and should not result in a reduction in retail sales.

The free and restricted percentages established by this rule provide the market with optimum supply and apply uniformly to all regulated handlers in the industry, regardless of size. As the restriction represents a percentage of a handler's volume, the costs, when applicable, are proportionate and should not place an extra burden on small entities as compared to large entities.

The stabilizing effects of this action benefit all handlers by helping them maintain and expand markets, despite seasonal supply fluctuations. Likewise, price stability positively impacts all growers and handlers by allowing them to better anticipate the revenues their tart cherries will generate. Growers and handlers, regardless of size, should benefit from the stabilizing effects of this restriction. In addition, the increased carry-out should provide

processors enough supply to meet market needs going into the next season.

The Board considered some alternatives in its preliminary restriction discussions that affected this recommended action. The first alternative concerned the average sales in estimating demand for the coming season, and the second alternative regarded the recommended carry-out figure.

Regarding demand, the Board began with the actual sales average of 198 million pounds. There was concern, however, that this value, which incorporated the weather-related crop failure of 2012, would result in an over-restrictive calculation. After considering options in the range of 24 to 52 million pounds, the Board determined that an adjustment of 52 million pounds, to reach an average demand of 250 million pounds, was most appropriate for the industry. Thus, the other alternatives were rejected, and the Board recommended the 52 million pound economic adjustment.

Regarding the carry-out value, the Board considered keeping this value at the order's 20 million pound maximum. However, many noted that the industry now regularly carries over more volume than in the past to keep its expanded product lines supplied at the end of the season. One member noted that even at the end of the disaster season, there were 17 million pounds carried out. Another noted that the 81 million pound carry-in this season was seen as burdensome. Others were concerned that in addition to the previous adjustment, too high of a carry-out figure might discourage using reserves to protect the industry from another disaster. The Board considered 60 million pounds and 30 million pounds, but these were considered respectively too large and too restrictive and thus were rejected. The Board then reached a consensus and recommended the Secretary increase the maximum carry-out to 50 million pounds for the 2014–2015 season alone.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0177, Tart Cherries Grown in the States of MI, NY, PA, OR, UT, WA, and WI. No changes in those requirements as a result of this action are necessary. Should any changes become necessary, they would be submitted to OMB for approval.

This action will not impose any additional reporting or recordkeeping requirements on either small or large tart cherry handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

As noted in the initial regulatory flexibility analysis, USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this final rule. Further, the public comment received concerning the proposal did not address the initial regulatory flexibility analysis.

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

In addition, the Board's meeting was widely publicized throughout the tart cherry industry and all interested persons were invited to attend the meeting and participate in Board deliberations on all issues. Like all Board meetings, the June 26, 2014, and September 11, 2014, meetings were public meetings and all entities, both large and small, were able to express views on this issue.

A proposed rule concerning this action was published in the **Federal Register** on February 19, 2015 (80 FR 8817). Copies of the rule were mailed, emailed, or sent by facsimile to all Board members and tart cherry handlers. Finally, the rule was made available through the Internet by USDA and the Office of the Federal Register. A 30-day comment period ending March 23, 2015, was provided to allow interested persons to respond to the proposal.

One negative comment was received during the comment period. The concerns expressed in the negative comment pertained to pending litigation or to issues not applicable to the proposed rule. Additionally, the commenter did not provide any alternatives for consideration. Accordingly, no changes will be made to the rule as proposed, based on the comment received.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/MarketingOrdersSmallBusinessGuide.* Any questions about the compliance guide should be sent to Jeffrey Smutny at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant matter presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

It is further found that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** (5 U.S.C. 553) because handlers are already shipping tart cherries from the 2014–2015 crop. Further, handlers are aware of this rule, which was recommended at a public meeting. Also, a 30-day comment period was provided for in the proposed rule.

List of Subjects in 7 CFR Part 930

Marketing agreements, Reporting and recordkeeping requirements, Tart cherries.

For the reasons set forth in the preamble, 7 CFR part 930 is amended as follows:

PART 930—TART CHERRIES GROWN IN THE STATES OF MICHIGAN, NEW YORK, PENNSYLVANIA, OREGON, UTAH, WASHINGTON, AND WISCONSIN

■ 1. The authority citation for 7 CFR part 930 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 930.151 is added to read as follows:

§ 930.151 Desirable carry-out inventory.

For the crop year beginning on July 1, 2014, the desirable carry-out inventory, for the purposes of determining an optimum supply volume, will be 50 million pounds.

■ 3. Section 930.256 is added to read as follows:

§ 930.256 Free and restricted percentages for the 2014–15 crop year.

The percentages for tart cherries handled by handlers during the crop year beginning on July 1, 2014, which shall be free and restricted, respectively, are designated as follows: Free percentage, 80 percent and restricted percentage, 20 percent.

Dated: May 21, 2015.

Rex A. Barnes,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2015–12762 Filed 5–29–15; 8:45 am]

BILLING CODE 3410–02–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2014–0275]

RIN 3150–AJ52

List of Approved Spent Fuel Storage Casks: Holtec HI–STORM Flood/Wind System; Certificate of Compliance No. 1032, Amendment No. 1, Revision 1

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is confirming the effective date of June 2, 2015, for the direct final rule that was published in the **Federal Register** on March 19, 2015. This direct final rule amended the NRC's spent fuel storage regulations by revising the Holtec International, Inc. (Holtec), HI–STORM Flood/Wind (FW) System listing within the ''List of approved spent fuel storage casks'' to add Amendment No. 1, Revision 1, to Certificate of Compliance (CoC) No. 1032. Amendment No. 1, Revision 1, allows these casks to accept 14X14B fuel assemblies with minor changes in the internal diameter of the fuel cladding, diameter of the fuel pellet, and spacing between the fuel pins. The amendment also updates testing requirements for the fabrication of Metamic HT neutron-absorbing structural material.

DATES: *Effective date:* The effective date of June 2, 2015, for the direct final rule published March 19, 2015 (80 FR 14291), is confirmed.

ADDRESSES: Please refer to Docket ID NRC–2014–0275 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2014–0275. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.*

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Robert D. MacDougall, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–5175; email: *Robert.MacDougall@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Discussion

On March 19, 2015 (80 FR 14291), the NRC published a direct final rule amending its regulations in § 72.214 of Title 10 of the *Code of Federal Regulations* (10 CFR) by revising the Holtec HI–STORM FW System listing within the ''List of approved spent fuel storage casks'' to add Amendment No. 1, Revision 1, to CoC No. 1032. Amendment No. 1, Revision 1, allows these casks to accept 14X14B fuel assemblies with minor changes in the internal diameter of the fuel cladding, diameter of the fuel pellet, and spacing between the fuel pins. The amendment also updates testing requirements for the fabrication of Metamic HT neutron-absorbing structural material.

II. Public Comments on the Companion Proposed Rule

In the direct final rule, the NRC stated that if no significant adverse comments were received, the direct final rule would become effective on June 2, 2015. The NRC received eight public comments from private citizens on the companion proposed rule (80 FR 14332). Electronic copies of these comments can be obtained from the Federal rulemaking Web site, *http://www.regulations.gov,* by searching for Docket ID NRC–2014–0275. The comments also are available in ADAMS under Accession Nos. ML15113B266, ML15113B275, ML15141A021, ML15119A201, ML15119A206, ML15119A210, ML15119A214, and ML15119A230. For the reasons discussed in more detail in Section III, ''Public Comment Analysis,'' of this document, none of the comments received are considered significant adverse comments.

III. Public Comment Analysis

The NRC received eight comments from private citizens on the proposed rule, many raising multiple and overlapping issues. As explained in the March 19, 2015, direct final rule, the NRC would withdraw the direct final rule only if it received a ''significant adverse comment.'' This is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

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

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

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

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

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

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

The NRC determined that none of the comments submitted on this direct final rule met any of these criteria. The comments either were already addressed by the NRC staff's safety evaluation report (SER) (ADAMS Accession No. ML14276A620), were beyond the scope of this rulemaking, or failed to provide a reason sufficient to require a substantive response in a notice-and-comment rulemaking. The NRC has not made any changes to the direct final rule as a result of the public comments. However, the NRC is taking this opportunity to respond to the individual comments to clarify information about the CoC rulemaking process.

For rulemakings amending or revising a CoC, the scope of the rulemaking is limited to the specific changes requested by the applicant in the request for the amendment or amendment revision. Therefore, comments about the system, or spent fuel storage in general, that are not applicable to the changes requested by the applicant are outside the scope of

this rulemaking. Comments about details of the particular system that is the subject of the rulemaking, but that are not being addressed by the specific changes requested, have already been resolved in prior rulemakings. Persons who have questions or concerns about prior rulemakings and the resulting final rules may consider the NRC's process for petitions for rulemaking under 10 CFR 2.802. Additionally, safety concerns about any NRC-regulated activity may be reported to the NRC in accordance with the guidance posted on the NRC's public Web site at *http://www.nrc.gov/about-nrc/regulatory/allegations/safety-concern.html.* This Web site provides information on how to notify the NRC of emergency or non-emergency issues.

The NRC identified 12 overall issues raised in the comments, and the NRC's responses to these issues follow.

Issue 1: Stress Corrosion Cracking

Multiple commenters raised the issue of the potential for premature failure of the multi-purpose canisters (MPCs) containing spent fuel within Holtec casks due to stress corrosion cracking (SCC) of the MPC's stainless steel walls. One commenter cited evidence that similar Holtec canisters at Diablo Canyon have already shown conditions for chloride-induced SCC after having been loaded with fuel for only 2 years. Another commenter noted that thin-walled canisters like the Holtec design do not have American Society of Mechanical Engineers (ASME) certification and do not meet ASME standards. Another commenter asked whether the NRC's seismic analysis assumes that the MPC's ½ inch-thick walls remain intact. Still another commenter asked the NRC to specify the extent of cracking from SCC that would require replacement of an MPC to ensure that the spent fuel inside would remain protected in a large earthquake or tsunami and associated mud flooding event. Another commenter alleged that although there is no seismic rating for cracked spent fuel storage canisters, the NRC plans to allow up to a 75 percent crack in these canisters.

NRC Response

These comments are not within the scope of this specific rulemaking. This rulemaking makes no changes to this system other than those identified in the revisions previously described. Other aspects of this system not identified in the revisions are not considered part of this rulemaking activity. These other aspects of the system were previously evaluated by the NRC as part of the original certification of the HI–STORM FW System dated March 28, 2011 (ADAMS Accession No. ML103020151). The NRC's evaluation and approval of the certification of the original HI–STORM FW System included an evaluation of the susceptibility to, and effects of, stress corrosion cracking and other corrosion mechanisms on safety-significant systems for spent nuclear fuel (SNF) dry cask storage (DCS) systems during an initial 20-year certification period. As indicated in the supporting SER for the original certification, the NRC staff determined that the HI–STORM FW System, when used within the requirements of the proposed CoC, will safely store SNF and prevent radiation releases and exposure in compliance with regulatory requirements. None of the revisions being made by this rule have any impact on the NRC staff's prior analysis in this area.

Regarding the ASME certification issue, the NRC's regulations in 10 CFR part 72 do not require DCS system canisters to be ASME-certified. However, the ASME Code requirements are often contained within the TSs that a general licensee is required to follow. As for the assertions that the NRC's ''plans to allow up to a 75 percent crack in these canisters,'' and that there is evidence of potential cracking or failing of canisters at Diablo Canyon, the NRC has no such plan and is unaware of any such evidence. Importantly, general licensees (10 CFR part 50 licensees that store spent fuel under a general 10 CFR part 72 license) are required to have programs in place to monitor and address any such issues should they arise. For example, 10 CFR 72.122(h)(4) requires storage confinement systems to have the capability for continuous monitoring in a manner such that the licensee will be able to determine when corrective action needs to be taken to maintain safe storage conditions.

Issue 2: Inspection Challenges and Inspection Access

Several commenters questioned the ability of the HI–STORM FW System to be adequately inspected and repaired if necessary during the initial certification period of 20 years, especially if the system is used in a coastal environment where SCC could be an issue.

On the issue of available methods for inspecting SCC, one commenter asserted that no technology exists to inspect adequately the exterior of thin welded canisters for cracks or other corrosion. The commenter said that the NRC is allowing vendors 5 years to develop an inspection method, but it will be limited, and the NRC plans to require inspection of only one canister per plant after 25 years and then the same canister at 5 years intervals. The commenter referred to an unnamed independent July 2010 report on the challenges and limitations of inspecting for SCC in stainless steel components other than loaded spent fuel dry storage canisters. The commenter asserted that no inspection method currently exists for loaded spent fuel dry storage canisters, and that the method recommended in the report as the most reliable is not possible with such canisters. Another commenter noted that if removal of the canister is the only way to inspect the bottom of a canister that has been in contact with the bottom of the concrete well, it will be unlikely that each canister will be inspected for corrosion between the canister and its concrete well, if current NRC inspection schedules for dry storage casks are followed.

Concerned about the frequency and extent of inspections, a commenter noted the limited number of dry storage canisters that have been inspected to date, and expressed concern that there will be very few canister inspections, and probably only one, performed at each installation site, with the first inspection occurring 20 years after deployment. The commenter suggested that sites prone to ground water intrusion should have annual visual inspections of the bottom of each canister.

NRC Response

These comments are not within the scope of this specific rulemaking. This rulemaking is limited to the revisions previously described. Furthermore, the NRC has evaluated the design of the HI–STORM FW System in the initial certification of this system and determined that the design is robust, and contains numbers of layers of acceptable confinement systems in compliance with 10 CFR part 72 requirements. In making this finding, the NRC staff evaluated the HI–STORM FW System to the specific overall requirements of 10 CFR 72.122. Additionally, the two canisters used in the HI–STORM FW System are the same as those used in the HI–STORM Underground Maximum Capacity (UMAX) Canister Storage System previously approved by the NRC (see 80 FR 12073, dated March 6, 2015). Therefore, a detailed evaluation of this MPC system is also documented in the NRC staff's SER for the HI–STORM UMAX System (ADAMS Accession No. ML14122A441). In that review, the NRC staff noted that the current technology does provide options for inspection if necessary.

Issue 3: Unavailability of Hot Cells or Spent Fuel Pools To Transfer or Store Spent Fuel From a Damaged Canister

One commenter noted that no spent fuel storage cask has ever been opened and examined. Another pointed out that no ''hot cells'' (dry transfer systems) exist in the United States that are large enough to transfer spent fuel between canisters. Another asked how Holtec would handle the failure of a hypothetical 50 canisters after a major earthquake.

Yet another commenter expressed concern that the spent fuel pools at the decommissioning San Onofre Nuclear Generating Station (SONGS) will be demolished once the reactors' spent fuel is in dry casks. Demolition of the spent fuel pools, the commenter wrote, would essentially negate the chances of repackaging any casks leaking radionuclides without another major construction effort to build a new storage pool. Another commenter wrote that a spent fuel storage pool is required to replace canisters and casks at any reactor site with spent fuel in dry storage, and that transporting cracked canisters to another facility with a pool presents numerous safety risks.

NRC Response

These comments are not within the scope of this specific rulemaking. This rulemaking is limited to the specific revisions to Amendment No. 1 of the HI–STORM FW System. This rulemaking does not propose any change in the standards for approval of a CoC, or the requirements that govern use of the CoC by a general licensee. In 10 CFR parts 50 and 72, the NRC places the responsibility for providing facilities necessary to perform spent fuel transfers between canisters, and store spent fuel removed from a damaged or defective MPC, with the 10 CFR part 50 licensee, not the canister system manufacturer. Moreover, in its March 28, 2011, SER for the CoC for the original HI–STORM FW System, the NRC staff evaluated and found acceptable a key subsystem of the applicant's storage system, the HI–TRAC Variable Weight (VW) transfer cask, for its operability with hot cells. In the March 28, 2011, SER, the NRC staff stated that ''[t]he HI–TRAC VW transfer cask also allows dry loading (or unloading) of SNF into the MPC in a hot cell.''

Finally, the NRC has not approved the demolition of the spent storage pools at SONGS. The decommissioning of the SONGS facility will be conducted pursuant to the NRC's decommissioning regulations which include opportunities for public involvement. (See 10 CFR part 20, subpart E; 10 CFR 50.75 and 50.82; 10 CFR 51.53 and 51.95). More information about the SONGS decommissioning activities can be found on the NRC's public Web site at *http://www.nrc.gov/info-finder/reactor/songs/decommissioning-plans.html.*

Issue 4: Seismic Protection

Several comments raised concerns regarding the ability of this CoC system to withstand seismic events, particularly if the system were to be used at specific sites with known seismic activity, such as SONGS. There is also a question of whether the Holtec casks at issue have been fully tested to handle all United States seismic conditions, particularly those in California. One commenter contended that the NRC lacks information to support a sound determination on whether the casks could withstand the vertical and horizontal ground acceleration and significant ground displacement from a sizable earthquake on one of California's known faults. Another commenter expressed a belief that the NRC has not adequately responded to concerns the U.S. Geological Survey pointed out in comments on the ''Fukushima Lessons Learned'' process.

NRC Response

These comments are not within the scope of this specific rulemaking. This rulemaking is limited to the specific revisions to Amendment No. 1 of the HI–STORM FW System. Additionally, as explained when the NRC addressed a similar comment about the ability of HI–STORM casks to withstand seismic events during the UMAX System certification rulemaking, the certification provided by approval of the HI–STORM FW System does not, in and of itself, authorize use of this system at any specific site. Under 10 CFR 72.212(b)(5), before applying the changes authorized by an amended CoC and loading a cask, a general licensee wishing to use this cask system must perform written evaluations to establish, among other things, that:

- Cask storage pads and areas have been designed to adequately support the static and dynamic loads of the stored casks, considering potential amplification of earthquakes through soil-structure interaction, and soil liquefaction potential or other soil instability due to vibratory ground motion; and
- The independent spent fuel storage installation at the reactor site where the casks will be located will meet the requirements of 10 CFR 72.104 to ensure that radiation doses beyond the reactor's controlled area do not exceed 0.25 mSv (25 mrem) to the whole body, 0.75 mSv (75 mrem) to the thyroid and 0.25 mSv (25 mrem) to any other critical organ, and are further to controlled to a level as low as is reasonably achievable.

In addition, under 10 CFR 72.212(b)(6), before using the general license, the reactor licensee must review the Safety Analysis Report (SAR) referenced in the CoC or amended CoC and the NRC's SER evaluating the SAR to determine whether the reactor site parameters, including analyses of earthquake intensity and tornado missiles, are enveloped by the cask design bases considered in these reports.

The seismic design levels of the HI–STORM FW System as provided in Amendment No. 1, Revision 1, of this CoC are acceptable for most areas in the continental United States. For locations with potential for seismic activity beyond those analyzed for this system, additional NRC evaluations and certifications may be required before the system may be used in those locations. The NRC is currently evaluating another HI–STORM UMAX System amendment request that provides additional analysis intended to ensure the system's integrity during an earthquake with higher seismic demands.

Issue 5: Unacceptable Definition of ''Undamaged''

One commenter said that corrosion, pitting, and cracks cannot be considered undamaged.

NRC Response

This comment is not within the scope of this specific rulemaking. This rulemaking is limited to the specific revisions to Amendment No. 1 of the HI–STORM FW System. To the extent that the comment is intended to raise safety concerns with the change in the definition of damaged fuel, the definition would not be affected by this rulemaking and is therefore not within its scope. The purpose of the definition of damaged fuel is to identify conditions under which additional engineering measures are required to confine and secure the spent fuel before it can be loaded into a DCS system. The requirement to use these measures, which include isolating the affected spent fuel assembly in an additional container before loading it into an MPC, apply to all fuel assemblies, although the definition of ''damaged'' fuel may be revised to address calculated strengths or known weaknesses in a given assembly design. The NRC staff evaluated and found acceptable a proposed change in the definition of damaged fuel in the SER to CoC No.

1032, Amendment No. 1, dated December 17, 2014 (ADAMS Accession No. ML14351A475). The NRC staff evaluated the safety of this revision to CoC No. 1032, Amendment No. 1, in the SER dated March 13, 2015 (ADAMS Accession No. ML14276A620). No information is provided that would cause the NRC to change its conclusion regarding the safety of this change in the definition of damaged fuel as documented in the SER.

Issue 6: How will casks be removed from service?

One commenter pointed out that for any cask placed into service during the final renewal term of a CoC, or during the remaining term of a CoC that was not renewed, the general license for that cask must terminate after a storage period not to exceed the term specified by the cask's CoC, generally 20 years. The commenter further noted that when the general license expires, all casks subject to it must be removed from service. The commenter asked how a cask can be removed from service after its licensed service life of 20 years if the cask contains still-hot radioactive waste, given the fact that, according to Holtec's chief executive officer, its canisters are not capable of being repackaged.

NRC Response

This comment is not within the scope of this specific rulemaking. This rulemaking is limited to the specific revisions to Amendment No. 1 of the HI–STORM FW System. The regulations governing the length of the CoC term, the standards for approval of a CoC, or the requirements that govern use of the CoC by a general licensee, are not within the changes proposed by this rule.

As to the specific comments, the NRC cannot verify the basis for comments attributed to Holtec's chief executive officer. Importantly, however, the NRC's regulations require that the systems be designed to allow for retrieval of spent fuel, and that the waste is packaged in a manner that allows handling and retrievability without the release of radioactive material above regulatory limits. (See 10 CFR 72.122(h)(5) and (l)). The HI–STORM FW System is designed to meet this requirement, and the NRC staff approved this design in its SER dated March 28, 2011 (ADAMS Package Accession No. ML103020135).

Issue 7: Inadequate Tsunami Analysis

One commenter expressed concern about the NRC's process for certifying that the Holtec cask system will operate as designed after a tsunami. The commenter requested a detailed tsunami recovery procedure that should include a means to ensure that muds, salts, and other chemicals within the infiltrating tsunami water have not damaged the stainless steel canister or reduced the DCS's longevity.

NRC Response

This comment is not within the scope of this specific rulemaking. This rulemaking is limited to the specific revisions to Amendment No. 1 of the HI–STORM FW System. The NRC staff previously evaluated the impacts of flooding during the review of the initial certification for the HI–STORM FW System.

In its March 28, 2011, SER (see Sections 4.8.2 and 7.3.1) for the initial certification of the HI–STORM FW System, the NRC staff considered both full and partial flooding for both the vertical and horizontal positions for the MPC. The NRC staff found that the fully flooded condition would produce the highest reactivity in the spent fuel, and that the fully flooded model for safety evaluations ''is acceptable and applicable to all of the assembly configurations that are to be stored in the HISTORM FW MPC Storage system,'' including damaged fuel configurations.

In its March 28, 2011, SER, the NRC staff also noted the system's design measures to limit the rise in fuel cladding temperature under the most adverse flood event (one with a water level just high enough to block the MPC overpack's air convection inlet duct). The changes requested in this revision do not affect the NRC's prior flooding evaluation for the initial certification of this system.

Issue 8: High Burnup Fuel

One commenter said that no vendor has addressed how a cask will handle high burnup fuel (HBF) cladding that may degrade shortly after dry storage. This commenter noted that HBF burns longer in the reactor, resulting in spent fuel more than twice as radioactive, hotter, and unpredictable in storage and transport. The commenter further asserted that HBF requires more years to cool in a reactor's spent fuel storage pool before it can be transported. This raises questions about the long-term acceptability of extended storage of HBF, according to the commenter.

NRC Response

The comment is not within the scope of this specific rulemaking. This rulemaking is limited to the specific revisions in Amendment No. 1 to the HISTORM FW System. In its March 28, 2011, SER for the original certification for the HI–STORM FW System, the NRC previously evaluated the acceptability of storing HBF during the system's initial 20-year certification term. The revision authorized by this direct final rule does not affect that original evaluation. Storage beyond the initial term of 20 years will require the applicant to submit a license renewal application. The application for that CoC renewal must include, among other things, a description of the Aging Management Programs for management of issues associated with aging that could adversely affect structures, systems, and components important to safety. (See 10 CFR 72.240(c)(3)).

Issue 9: Need for New Environmental Impact Statement (EIS)

One commenter asked that the NRC do a full EIS evaluating the Holtec cask as one alternative, a German cask as another, and a French cask as a third, with possibly an additional alternative.

NRC Response

This comment does not present information that would result in a determination that this revision requires an EIS, rather than an Environmental Assessment (EA). According to the National Environmental Policy Act (NEPA) and the NRC's regulations in 10 CFR part 51, an EIS is only required if the action involves a major federal action significantly affecting the quality of the human environment. The NRC's regulations in 10 CFR part 51 identify actions that require an EIS (see 10 CFR 51.20). Certificate of compliance rulemakings are not one of those actions. Instead, for CoC rulemakings, the NRC performs an EA to determine whether the action will result in a significant environmental impact. If an EA determines that the action will result in a significant impact, the agency prepares an EIS. However, if the EA concludes with a ''finding of no significant impact'' (FONSI), an EIS does not need to be prepared.

As explained in the March 19, 2015, direct final rule, the EA regarding the revision to Amendment No. 1 of HI–STORM FW System, concluded with a FONSI and therefore, an EIS is not required for this action. This comment presents no new information or analysis that would justify reconsidering the agency's FONSI determination.

Issue 10: Metamic Fabrication Testing Requirements

One commenter objected that Amendment No. 1, Revision 1, of the HI–STORM FW System CoC would remove fabrication testing requirements for the thermal expansion coefficient

and thermal conductivity of Metamic HT neutron-absorbing structural material. The commenter noted that the justification for this change is that these properties have little variability when Metamic HT is fabricated according to the manufacturer's manual. The commenter asked the NRC what it thinks testing is for if not to verify that the product has been made according to the specifications in the manufacturer's manual.

NRC Response

This issue was addressed by the NRC staff in its SER, and the commenters do not raise any additional information that would alter the staff's determination that the HI–STORM FW System, Amendment No. 1, Revision 1, casks, when used within the requirements of the proposed CoC, will safely store SNF. In its March 19, 2015, SER (ADAMS Accession No. ML14276A620), the NRC staff concluded that this was acceptable for this specific application. For a detailed discussion regarding the NRC staff's evaluation, see Section 4 of the SER.

Issue 11: Exemptions

One commenter contended that a general licensee seeking to load spent nuclear fuel into the Holtec HI–STORM FW System in accordance with the changes described in this rulemaking would have to request an exemption from the requirements of 10 CFR 72.212 and 72.214. Another commenter asserted that once Holtec has been given its original CoC, there should be no ''exemptions.''

NRC Response

The revisions to Amendment No. 1 of CoC 1032 for the HI–STORM FW System is to provide changes to the cask system so that general licensees do not need to request an exemption from any requirements of 10 CFR 72.212 or 10 CFR 72.214. Like all other proposed CoC amendments or revisions, the general licensee under 10 CFR 72.212(b)(5) will have to perform written evaluations which establish that the cask will conform to the terms, conditions, and specifications of a CoC or an amended CoC listed in § 72.214.

Issue 12: Reduced Circulation of Air for Cooling

Two commenters objected that the proposed change in the HI–STORM FW System CoC would restrict the circulation of air for cooling spent fuel within the MPC or cask.

NRC Response

The NRC staff evaluated this issue as part of its SER and concluded that there is no significant reduction in the cooling capacity of the HI–STORM FW System as a result of the revisions requested by the applicant. The NRC staff's SER determined that CoC 1032, Amendment No. 1, Revision 1, casks, when used within the requirements of the CoC, will safely store SNF. The comment presents no information that the NRC has not already considered, or that would cause the NRC to change its analysis.

The purpose of the revision is to permit the more compact spent fuel assemblies now in some reactors' spent fuel storage pools to be loaded into the HI–STORM FW System for dry storage. In its March 19, 2015, SER (ADAMS Accession No. ML14276A620), the NRC staff found that approval of the application would permit a volumetric increase of 0.6 percent of the fuel and a reduction of 0.13 percent of the original flow area of the 14-rod-by-14-rod fuel assembly previously approved for use in this cask system. The NRC staff also found, however, that the reduced flow area through the 14x14B fuel assembly ''is still larger than the 17x17 assembly flow area used as the bounding scenario in the thermal analysis. As a result, the flow resistance factor is still less restrictive than the one used in the bounding scenario, and the passive decay heat removal of the proposed 14x14B assembly is still conservative.'' The NRC staff also found that the spent fuel cladding ''continues to be protected against degradation leading to gross ruptures under long-term storage by maintaining cladding temperatures below 752 °F (400 °C),'' and ''continues to be protected against degradation leading to gross ruptures under off-normal and accident conditions by maintaining cladding temperatures below 1058 °F (570 °C). Protection of the cladding against degradation is expected to allow ready retrieval of spent fuel for further processing or disposal.''

Therefore, the NRC staff has concluded that the comments received on the companion proposed rule for the HI–STORM FW System, Amendment No. 1, Revision 1, are not significant adverse comments as defined in NUREG–BR–0053, Revision 6, ''United States Nuclear Regulatory Commission Regulations Handbook'' (ADAMS Accession No. ML052720461). Therefore, this rule will become effective as scheduled.

Dated at Rockville, Maryland, this 27th day of May, 2015.

For the Nuclear Regulatory Commission.

Leslie Terry,

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

[FR Doc. 2015–13081 Filed 5–29–15; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0342; Directorate Identifier 2014–NM–007–AD; Amendment 39–18168; AD 2015–11–05]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 747–400, 747–400D, 747–400F, 747–8F, and 747–8 series airplanes. This AD was prompted by reports of very high temperatures, near the floor in the aft lower lobe cargo compartment. This AD requires installing an additional zone temperature sensor (ZTS) assembly in the aft cargo compartment, and, for certain airplanes, installing tape and replacing the markers in the bulk cargo compartment. We are issuing this AD to prevent overheating of the aft lower lobe cargo compartment, where, if temperature sensitive cargo is present, the release of flammable vapors could result in a fire or explosion if exposed to an ignition source.

DATES: This AD is effective July 6, 2015.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of July 6, 2015.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view this 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. It is also available on the Internet at *http://www.regulations.gov* by searching for

and locating Docket No. FAA–2014–0342.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0342; 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 address for the Docket Office (phone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Susan Monroe, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, 1601 Lind Avenue SW., Renton, WA; phone: 425–917–6457; fax: 425–917–6590; email: *susan.l.monroe@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 747–400, 747–400D, 747–400F, 747–8F, and 747–8 series airplanes. The NPRM published in the **Federal Register** on June 25, 2014 (79 FR 35968). The NPRM was prompted by reports of very high temperatures, up to 67 degrees Celsius (152 degrees Fahrenheit), near the floor in the aft lower lobe cargo compartment on certain Model 747 airplanes. The NPRM proposed to require installing an additional ZTS in the aft cargo compartment. For certain airplanes, the NPRM proposed to first require installing tape and replacing the markers in the bulk cargo compartment, unless terminated by the early installation of the ZTS. We are issuing this AD to prevent overheating of the aft lower lobe cargo compartment, where, if temperature sensitive cargo is present, the release of flammable vapors could result in a fire or explosion if exposed to an ignition source.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM (79 FR 35968, June 25, 2014) and the FAA's response to each comment.

Request To Clarify ''Required for Compliance'' (RC) Steps

United Airlines (UA) asked that we clarify the actions required in the NPRM (79 FR 35968, June 25, 2014) by adding instructions for steps labeled, and not labeled, as ''RC'' in the required service information. UA did not provide a reason for this request.

We infer that the commenter is referring to Boeing Special Attention Service Bulletin 747–21–2550, dated December 6, 2013, which includes ''RC'' language. (Boeing Special Attention Service Bulletin 747–21–2544, Revision 2, dated December 11, 2014, does not include ''RC'' language.) We acknowledge the commenter's request and provide the following clarification.

The actions specified in Boeing Special Attention Service Bulletin 747–21–2550, dated December 6, 2013, include steps that are identified as RC because these steps have a direct effect on detecting, preventing, resolving, or eliminating an identified unsafe condition. Therefore, for service information that incorporates the RC concept, steps that are identified as RC, including substeps and identified figures, must be done to comply with the AD. The RC concept does not apply to Boeing Special Attention Service Bulletin 747–21–2544, Revision 2, dated December 11, 2014, which does not include any RC steps. We have added a new paragraph (j)(4) in this AD to describe the RC concept.

Request To Clarify Certain Language in the Summary Section

Boeing asked that we clarify certain language in the Summary section of the NPRM (79 FR 35968, June 25, 2014) to specify that the solution to the unsafe condition is the installation of a ''zone temperature sensor assembly,'' rather than a ''zone temperature sensor.'' Boeing stated that the ZTS is a component within the ZTS assembly, and added that omitting the word ''assembly'' could confuse operators.

We agree with the commenter for the reason provided. We have included the word ''assembly'' after references to the ZTS in the SUMMARY of this final rule.

Request To Clarify Certain Language in the Discussion Section

Boeing asked that we clarify the first sentence of the Discussion section of the NPRM (79 FR 35968, June 25, 2014) to specify that the high temperatures near the floor in the aft lower lobe cargo compartment were found only on certain Model 747 airplanes. Boeing stated that the wording in the NPRM is too broad for the investigation that took place.

We agree with the request. We have changed the Discussion section of this final rule accordingly.

Boeing also asked that we clarify the following sentence of the Discussion section of the NPRM (79 FR 35968, June 25, 2014): ''Under these conditions, the switches will not command the system valves properly, and the switches may fail to shut off the flow of hot air to the lower lobe cargo compartment, causing compartment temperatures to rise beyond 60 degrees Celsius (140 degrees Fahrenheit).'' Boeing asked that the word ''will'' be changed to ''may'' in that sentence, because the blockage condition does not guarantee that the temperature switches will not control the system properly.

We acknowledge and agree with the commenter's concern. However, since that level of detail does not reappear in a final rule, no change to this final rule is necessary in this regard.

Request To Require Additional Actions for Certain Airplanes

Boeing asked that airplanes having certain variable numbers specified in paragraph (g)(1) of the proposed AD (79 FR 35968, June 25, 2014) be required to accomplish the actions specified in paragraph (g)(2) of the proposed AD. Boeing stated that airplanes having those variable numbers might have had a partial installation done in production. Boeing also stated that in the next revision of Boeing Special Attention Service Bulletin 747–21–2544, the action for those airplanes will be a general visual inspection to determine if both markers and tape are installed, and installation of the markers and tape if necessary.

We agree with the commenter. Boeing Special Attention Service Bulletin 747–21–2544, Revision 2, dated December 11, 2014, has been issued and addresses the concerns identified by the commenter. Therefore, we have revised this final rule to remove paragraphs (g)(1) and (g)(2) of the proposed AD. We have also revised paragraph (g) of this AD to include Boeing Special Attention Service Bulletin 747–21–2544, Revision 2, dated December 11, 2014, as well as the option of contacting the FAA for an approval method to accomplish the actions. We have added Boeing Special Attention Service Bulletin 747–21–2544, Revision 1, dated September 30, 2013, to paragraph (i) of this AD.

Request To Remove Airplane Variable Number RC520

Boeing asked that we change paragraph (g)(1)(ii) of the proposed AD (79 FR 35968, June 25, 2014) to remove airplane variable number RC520

because it is not a valid airplane variable number.

We agree with the commenter for the reason provided. That airplane was identified in paragraph (g)(1)(ii) of the NPRM (79 FR 35968, June 25, 2014). That paragraph, as explained previously, is not included in this final rule.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously, except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (79 FR 35968, June 25, 2014) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (79 FR 35968, June 25, 2014).

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Special Attention Service Bulletin 747–21–2544, Revision 2, dated December 11, 2014; and Boeing Special Attention Service Bulletin 747–21–2550, dated December 6, 2013. The service information describes procedures for installing warning tape and markers in the bulk cargo compartment and installing an additional zone temperature sensor assembly in the aft cargo compartment. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this AD.

Costs of Compliance

We estimate that this AD affects 130 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Install ZTS assembly	91 work-hours × $85 per hour = $7,735	$7,545	$15,280	$1,986,400

We estimate the following costs to do the optional actions specified in this AD.

OPTIONAL COSTS

Action	Labor cost	Parts cost	Cost per product
Install tape and markers	1 work-hour × $85 per hour = $85	$33	$118

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):

2015–11–05 The Boeing Company: Amendment 39–18168; Docket No. FAA–2014–0342; Directorate Identifier 2014–NM–007–AD.

(a) Effective Date

This AD is effective July 6, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 747–400, 747–400D, 747–400F, 747–8F, and 747–8 series airplanes, certificated in any category, as identified in paragraphs (c)(1) and (c)(2) of this AD.

(1) Airplanes identified in Boeing Service Bulletin 747–21–2550, dated December 6, 2013.

(2) Airplanes identified in paragraph (h)(2) of this AD.

(d) Subject

Air Transport Association (ATA) of America Code 21, Air conditioning.

(e) Unsafe Condition

This AD was prompted by reports of very high temperatures, near the floor in the aft lower lobe cargo compartment. We are issuing this AD to prevent overheating of the aft lower lobe cargo compartment, where, if temperature sensitive cargo is present, the release of flammable vapors could result in a fire or explosion if exposed to an ignition source.

(f) Compliance

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

(g) Installation for Certain Airplanes (Interim Action)

Within 12 months after the effective date of this AD, remove the existing markers and install tape and new markers in the bulk cargo compartment, in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–21–2544, Revision 2, dated December 11, 2014; or using a method approved in accordance with the procedures specified in paragraph (j) of this AD, as applicable. Accomplishing the actions specified in paragraph (h) of this AD within 12 months after the effective date of this AD terminates the requirements of this paragraph.

(h) Installation for All Airplanes (Terminating Action)

Within 60 months after the effective date of this AD, install an additional zone temperature sensor assembly in the aft cargo compartment, as specified in paragraph (h)(1) or (h)(2) of this AD, as applicable. Doing this action within 12 months after the effective date of this AD terminates the requirements of paragraph (g) of this AD.

(1) For airplanes identified in Boeing Service Bulletin 747–21–2550, dated December 6, 2013: Do the actions in accordance with the Accomplishment Instructions of Boeing Service Bulletin 747–21–2550, dated December 6, 2013.

(2) For airplanes having variable numbers RC021 and RC573: Do the actions using a method approved in accordance with the procedures specified in paragraph (j) of this AD.

(i) Credit for Previous Actions

This paragraph provides credit for removing the existing markers and installing tape and new markers in the bulk cargo compartment, as required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Service Bulletin 747–21–2544, dated January 15, 2013; or Boeing Special Attention Service Bulletin 747–21–2544, Revision 1, dated September 30, 2013. This service information is not incorporated by reference in this AD.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle 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 paragraph (k)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) If the service information contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (j)(4)(i) and (j)(4)(ii) apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(k) Related Information

(1) For more information about this AD that is not incorporated by reference, contact Susan Monroe, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, 1601 Lind Avenue SW., Renton, WA; phone: 425–917–6457; fax: 425–917–6590; email: *susan.l.monroe@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Special Attention Service Bulletin 747–21–2544, Revision 2, dated December 11, 2014.

(ii) Boeing Special Attention Service Bulletin 747–21–2550, dated December 6, 2013.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.*

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on May 21, 2015.

John P. Piccola, Jr.,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–13018 Filed 5–29–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2015–N–1338]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Rectal Control System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the rectal control system into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the rectal control system's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective June 1, 2015. The classification was applicable on February 12, 2015.

FOR FURTHER INFORMATION CONTACT: Purva Pandya, Center for Devices and

Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G223, Silver Spring, MD 20993–0002, 240–402–9979, *purva.pandya@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1) of the FD&C Act. Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1), the person requests a classification under section 513(f)(2) of the FD&C Act. Under the second procedure, rather than first submitting a premarket notification under section 510(k) and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device. On June 23, 2014, Pelvalon, Inc., submitted a request for classification of the Eclipse System under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on February 12, 2015, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 876.5930.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a rectal control system will need to comply with the special controls named in this final order. The device is assigned the generic name rectal control system, and it is identified as a prescription device intended to treat fecal incontinence by controlling the size of the rectal lumen. The device is inserted in the vagina and includes a portion that expands to reduce the rectal lumen to prevent stool leakage and retracts to allow normal passage of stool. The device includes an external regulator to control the state of expansion.

FDA has identified the following risks to health associated specifically with this type of device, as well as the measures required to mitigate these risks in table 1.

TABLE 1—RECTAL CONTROL SYSTEM RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measures
Vaginal Wall Trauma	Clinical Testing Labeling.
Adverse Tissue Reaction	Biocompatibility Testing.
Infection	Non-Clinical (Bench) Testing Cleaning and Disinfection Validation Labeling.
Device Malfunction	Non-Clinical (Bench) Testing Labeling.
Urinary Urgency, Incontinence, or Voiding Problems	Clinical Testing Labeling.
Fecal Urgency or Difficulty in Evacuation	Clinical Testing Labeling.
Discomfort, Pain	Clinical Testing Labeling.
Change in Amount, Color, or Consistency of Vaginal Discharge	Labeling.

FDA believes that the following special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness:

- Clinical testing must document the device acceptance data and the adverse event profile associated with clinical use, and demonstrate that the device performs as intended under anticipated conditions of use.
- The elements of the device that contact vaginal tissue must be demonstrated to be biocompatible.
- The cleaning and disinfection instructions for the device must be validated.
- Non-clinical (bench) testing must demonstrate that the device performs as intended under anticipated conditions of use.

• Non-clinical (bench) testing must demonstrate that the device does not:

○ Enhance the growth of *Staphylococcus aureus.*

○ Increase production of Toxic Shock Syndrome Toxin-1 by *S. aureus.*

○ Alter the growth of normal vaginal flora.

• Labeling must include:

○ Specific instructions, contraindications, warnings, cautions, limitations, and the clinical training needed for the safe use of the device.

○ The intended patient population and the intended use environment.

○ Information on how the device is to be fitted, how the device operates, and recommendations on device maintenance.

○ A detailed summary of the clinical testing pertinent to the use of the device, including a summary of the device- and procedure-related complications or adverse events related to use of the device, as well as relevant safety and performance information.

• Patient labeling must be provided and must include:

○ Relevant contraindications, warnings, precautions, and adverse events/complications.

○ Information on how the device operates and the recommended device maintenance (*i.e.*, care instructions), including cleaning and disinfection.

○ Information on the patient population for which there was a favorable benefit/risk assessment.

○ The potential risks and benefits associated with the use of the device.

Rectal control system devices are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device; see 21 CFR 801.109 (*Prescription devices*).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the rectal control system they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other 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 part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910–0485.

IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov.*

1. DEN140020: De Novo Request per 513(f)(2) from Pelvalon, Inc., dated June 23, 2014.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 1. The authority citation for 21 CFR part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 876.5930 to subpart F to read as follows:

§ 876.5930 Rectal control system.

(a) *Identification.* A rectal control system is a prescription device intended to treat fecal incontinence by controlling the size of the rectal lumen. The device is inserted in the vagina and includes a portion that expands to reduce the rectal lumen to prevent stool leakage and retracts to allow normal passage of stool. The device includes an external regulator to control the state of expansion.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical testing must document the device acceptance data and the adverse event profile associated with clinical use, and demonstrate that the device performs as intended under anticipated conditions of use.

(2) The elements of the device that contact vaginal tissue must be demonstrated to be biocompatible.

(3) The cleaning and disinfection instructions for the device must be validated.

(4) Non-clinical (bench) testing must demonstrate that the device performs as intended under anticipated conditions of use.

(5) Non-clinical (bench) testing must demonstrate that the device does not:

(i) Enhance the growth of *Staphylococcus aureus.*

(ii) Increase production of Toxic Shock Syndrome Toxin-1 by *S. aureus.*

(iii) Alter the growth of normal vaginal flora.

(6) Labeling must include:

(i) Specific instructions, contraindications, warnings, cautions, limitations, and the clinical training needed for the safe use of the device.

(ii) The intended patient population and the intended use environment.

(iii) Information on how the device is to be fitted, how the device operates, and recommendations on device maintenance.

(iv) A detailed summary of the clinical testing pertinent to the use of the device, including a summary of the device- and procedure-related complications or adverse events related to use of the device, as well as relevant safety and performance information.

(7) Patient labeling must be provided and must include:

(i) Relevant contraindications, warnings, precautions, and adverse events/complications.

(ii) Information on how the device operates and the recommended device maintenance (*i.e.*, care instructions), including cleaning and disinfection.

(iii) Information on the patient population for which there was a favorable benefit/risk assessment.

(iv) The potential risks and benefits associated with the use of the device.

Dated: May 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13067 Filed 5–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2015–0447]

Drawbridge Operation Regulation; Mokelumne River, East Isleton, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the California Department of Transportation highway drawbridge across the Mokelumne River, mile 3.0, at East Isleton, CA. The deviation is necessary to allow the bridge owner to perform rehabilitation to the bridge control house. This deviation allows the bridge to remain in the closed-to-navigation position during the deviation period.

DATES: This deviation is effective from 10 p.m. on May 29, 2015 to 10 p.m. on June 26, 2015.

ADDRESSES: The docket for this deviation, [USCG–2015–0447], is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District; telephone 510–437–3516, email *David.H.Sulouff@uscg.mil.* If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: California Department of Transportation has requested a temporary change to the operation of the California Department of Transportation highway drawbridge across the Mokelumne River, mile 3.0, at East Isleton, CA. The drawbridge navigation span provides approximately 7 feet vertical clearance above Mean High Water in the closed-to-navigation position. In accordance with 33 CFR 117.175(a), the draw opens on signal from November 1 through April 30 from 9 a.m. to 5 p.m.; and from May 1 through October 31 from 6 a.m. to 10 p.m., except that during the following periods the draw need only open for recreational vessels on the hour, 20 minutes past the hour, and 40 minutes past the hour: Saturdays, 10 a.m. until 2 p.m.; Sundays, 11 a.m. until 6 p.m.; and Memorial Day, Fourth of July and Labor Day 11 a.m. until 6 p.m.. At all other times the drawbridge shall open on signal if at least 4 hours notice is given. Navigation on the waterway is commercial, recreational, search and rescue, and law enforcement.

The drawspan will be secured in the closed-to-navigation position from 10 p.m. on May 29, 2015 to 10 p.m. on June 26, 2015, due to rehabilitation of the bridge control house. This temporary deviation has been coordinated with the waterway users. Caltrans work plan and dates have been tailored to produce the least possible impacts to waterway traffic, land traffic, businesses and potential flood response plans, while allowing the work to be performed, to ensure dependable future operation of the drawbridge.

Vessels able to pass through the bridge in the closed position may do so at any time. The bridge will not be able to open for emergencies. Alternative paths for recreational vessel traffic are available via Little Potato Slough and Georgiana Slough. The Coast Guard will inform waterway users of this temporary deviation via our Local and Broadcast Notices to Mariners, to minimize resulting navigational impacts.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: May 19, 2015.

D.H. Sulouff,

District Bridge Chief, Commander, Eleventh Coast Guard District.

[FR Doc. 2015–13160 Filed 5–29–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2015–0234]

Safety Zone; San Francisco Giants Fireworks, San Francisco Bay, San Francisco, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the San Francisco Giants Fireworks display in the Captain of the Port, San Francisco area of responsibility during the dates and times noted below. This action is necessary to protect life and property of the maritime public from the hazards associated with the fireworks display. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone, unless authorized by the Patrol Commander (PATCOM).

DATES: The regulations in 33 CFR 165.1191, Table 1, Item number 1 will be enforced from 11 a.m. to 10:30 p.m. on June 26, 2015.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Lieutenant Junior Grade Joshua Dykman, U.S. Coast Guard Sector San Francisco; telephone (415) 399–3585 or email at *D11-PF-MarineEvents@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zones established in 33 CFR 165.1191, Table 1, Item number 1 on June 26, 2015. From 11 a.m. until 10 p.m. on June 26, 2015 the safety zone applies to the navigable waters around and under the fireworks barge within a radius of 100 feet during the loading, transit, and arrival of the fireworks barge at the launch site and until the start of the fireworks display. From 11 a.m. until 8:30 p.m. on June 26, 2015 the fireworks barge will be loading pyrotechnics at Pier 50 in San Francisco, CA. From 8:30 p.m. to 8:40 p.m. on June 26, 2015 the loaded fireworks barge will transit from Pier 50 to the launch site near Pier 48 in approximate position 37°46′40″ N., 122°22′58″ W. (NAD83). At the conclusion of the baseball game, approximately 10 p.m. on June 26, 2015, the safety zone will increase in size and encompass the navigable waters around and under the fireworks barge within a radius of 700 feet in approximate position 37°46′40″ N., 122°22′58″ W. (NAD83) for the San Francisco Giants Fireworks display in 33 CFR 165.1191, Table 1, Item number 1. Upon the conclusion of the fireworks display the safety zone shall terminate. This safety zone will be in effect from 11 a.m. to 10:30 p.m. on June 26, 2015.

Under the provisions of 33 CFR 165.1191, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone during all applicable

effective dates and times, unless authorized to do so by the PATCOM. Additionally, each person who receives notice of a lawful order or direction issued by an official patrol vessel shall obey the order or direction. The PATCOM is empowered to forbid entry into and control the regulated area. The PATCOM shall be designated by the Commander, Coast Guard Sector San Francisco. The PATCOM may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

This notice is issued under authority of 33 CFR 165.1191 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of the safety zone and its enforcement period via the Local Notice to Mariners.

If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notice, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: April 7, 2015.

Gregory G. Stump,

Captain, U.S. Coast Guard, Captain of the Port San Francisco.

[FR Doc. 2015–13132 Filed 5–29–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2015–0208]

Safety Zone; Fourth of July Fireworks, Berkeley Marina, San Francisco Bay, Berkeley, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the Berkeley Marina Fourth of July Fireworks display in the Captain of the Port, San Francisco area of responsibility during the dates and times noted below. This action is necessary to protect life and property of the maritime public from the hazards associated with the fireworks display. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone, unless authorized by the Patrol Commander (PATCOM).

DATES: The regulations in 33 CFR 165.1191, Table 1, Item number 8 will be enforced from 9:30 p.m. to 10 p.m. on July 4, 2015.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Lieutenant Junior Grade Joshua Dykman, U.S. Coast Guard Sector San Francisco; telephone (415) 399–3585 or email at *D11-PF-MarineEvents@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a 1,000 foot safety zone around the Berkeley Pier in approximate position 37°51′40″ N., 122°19′19″ W. (NAD 83) from 9:30 p.m. until 10 p.m. on July 4, 2015. Upon the commencement of the 30 minute fireworks display, scheduled to begin at 9:30 p.m. on July 4, 2015, the safety zone will encompass the navigable waters around and under the Berkeley Pier within a radius 1,000 feet in approximate position 37°51′40″ N., 122°19′19″ W. (NAD83) for the Fourth of July Fireworks, Berkeley Marina in 33 CFR 165.1191, Table 1, Item number 8. At the conclusion of the fireworks display the safety zone shall terminate. This safety zone will be in effect from 9:30 p.m. to 10 p.m. on July 4, 2015.

Under the provisions of 33 CFR 165.1191, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone during all applicable effective dates and times, unless authorized to do so by the PATCOM. Additionally, each person who receives notice of a lawful order or direction issued by an official patrol vessel shall obey the order or direction. The PATCOM is empowered to forbid entry into and control the regulated area. The PATCOM shall be designated by the Commander, Coast Guard Sector San Francisco. The PATCOM may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

This notice is issued under authority of 33 CFR 165.1191 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of the safety zone and its enforcement period via the Local Notice to Mariners.

If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notice, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: April 7, 2015.

Gregory G. Stump,

Captain, U.S. Coast Guard, Captain of the Port San Francisco.

[FR Doc. 2015–13138 Filed 5–29–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2015–0209]

Safety Zone; Fourth of July Fireworks, Crescent City, Crescent City Harbor, Crescent City, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the Crescent City Fourth of July Fireworks display in the Captain of the Port, San Francisco area of responsibility during the dates and times noted below. This action is necessary to protect life and property of the maritime public from the hazards associated with the fireworks display. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone, unless authorized by the Patrol Commander (PATCOM).

DATES: The regulations in 33 CFR 165.1191, Table 1, Item number 4 will be enforced from 9:30 p.m. to 10 p.m. on July 4, 2015.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Lieutenant Junior Grade Joshua Dykman, U.S. Coast Guard Sector San Francisco; telephone (415) 399–3585 or email at *D11-PF-MarineEvents@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone established in 33 CFR 165.1191, Table 1, Item number 4 on July 4, 2015. Upon commencement of the 30 minute fireworks display, scheduled to begin at 9:30 p.m. on July 4, 2015, the safety zone will encompass the navigable waters surrounding the land based launch site on the West Jetty of Crescent City Harbor within a radius of 700 feet in approximate position 41°44′41″ N., 124°11′59″ W. (NAD 83) for the Fourth of July Fireworks, Crescent City in 33 CFR 165.1191, Table 1, Item number 4. Upon the conclusion of the fireworks display the safety zone shall terminate. This safety zone will be in effect from 9:30 p.m. to 10 p.m. on July 4, 2015.

Under the provisions of 33 CFR 165.1191, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone during all applicable effective dates and times, unless authorized to do so by the PATCOM.

Additionally, each person who receives notice of a lawful order or direction issued by an official patrol vessel shall obey the order or direction. The PATCOM is empowered to forbid entry into and control the regulated area. The PATCOM shall be designated by the Commander, Coast Guard Sector San Francisco. The PATCOM may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

This notice is issued under authority of 33 CFR 165.1191 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of the safety zone and its enforcement period via the Local Notice to Mariners.

If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notice, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: April 23, 2015.

Gregory G. Stump,

Captain, U.S. Coast Guard, Captain of the Port San Francisco.

[FR Doc. 2015–13137 Filed 5–29–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2015–0210]

Safety Zone; Fourth of July Fireworks, City of Eureka, Humboldt Bay, Eureka, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the Fourth of July Fireworks, City of Eureka in the Captain of the Port, San Francisco area of responsibility during the dates and times noted below. This action is necessary to protect life and property of the maritime public from the hazards associated with the fireworks display. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone, unless authorized by the Patrol Commander (PATCOM).

DATES: The regulations in 33 CFR 165.1191, Table 1, Item number 3, will be enforced from 12 p.m. on July 3, 2015 through 10:40 p.m. on July 4, 2015.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Lieutenant Junior Grade Joshua Dykman, Sector San Francisco Waterways Safety Division, U.S. Coast Guard; telephone 415–399–3585, email *D11–PF-MarineEvents@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a safety zone in navigable waters around and under the fireworks barge within a radius of 100 feet during the loading, transit, and arrival of the fireworks barge to the display location and until the start of the fireworks display. From 12 p.m. on July 3, 2015 until 3 p.m. on July 4, 2015 the fireworks barge will be loaded off of Schneider Dock in Eureka, CA in approximate position 40°47′50″ N., 124°11′11″ W. (NAD 83). From 3 p.m. to 4 p.m. on July 4, 2015 the loaded barge will transit from Schneider Dock to the launch site off of Woodley Island near Eureka, CA at approximate position 40°48′29′ N., 124°10′06″ W. (NAD 83) where it will remain until the commencement of the fireworks display. Upon the commencement of the 25 minute fireworks display, scheduled to begin at 10 p.m. on July 4, 2015, the safety zone will increase in size to encompass the navigable waters around and under the fireworks barge within a radius 1,000 feet at approximate position 40°48′29″ N., 124°10′06″ W. (NAD 83) for the Fourth of July Fireworks, City of Eureka in 33 CFR 165.1191, Table 1, Item number 3. This safety zone will be in effect from 12 p.m. on July 3, 2015 until 10:40 p.m. on July 4, 2015.

Under the provisions of 33 CFR 165.1191, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone during all applicable effective dates and times, unless authorized to do so by the PATCOM. Additionally, each person who receives notice of a lawful order or direction issued by an official patrol vessel shall obey the order or direction. The PATCOM is empowered to forbid entry into and control the regulated area. The PATCOM shall be designated by the Commander, Coast Guard Sector San Francisco. The PATCOM may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so. This notice is issued under authority of 33 CFR 165.1191 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of the safety zone and its enforcement period via the Local Notice to Mariners.

If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notice, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: April 23, 2015.

Gregory G. Stump,

Captain, U.S. Coast Guard. Captain of the Port San Francisco.

[FR Doc. 2015–13133 Filed 5–29–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2015–0388]

RIN 1625–AA00

Safety Zone; Lakeside July 4th Fireworks, Lake Erie; Lakeside, OH

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary safety zone in the waters of Lake Erie in the vicinity of Lakeside, OH. This zone is intended to restrict vessels from a portion of Lake Erie during the fireworks event at Lakeside. This temporary safety zone is necessary to protect people and vessels from the hazards associated with this event.

DATES: This rule is effective from 9:30 p.m. until 10:45 p.m. on July 4, 2015.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2015–0388 and are available online by going to *www.regulations.gov,* inserting USCG–2015–0388 in the ''Keyword'' box, and then clicking ''search.'' They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground floor, Room W12–140, 1200 New Jersey Avenue SE., Washington DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary final rule, contact or email MST1 Brett A. Kreigh, U.S. Coast Guard Marine Safety Unit Toledo, at (419)418–6046 or *Brett.A.Kreigh@uscg.mil.* If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking
TFR Temporary Final Rule

A. Regulatory History and Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable and contrary to the public interest. The details of this emergent event were not received in sufficient time for the Coast Guard to solicit public comments before the start of the fireworks. Thus, waiting for a notice and comment period to run would inhibit the Coast Guard from protecting the public and vessels from the hazards associated with the maritime fireworks displays.

B. Basis and Purpose

The legal basis and authorities for this rule are found in 33 U.S.C. 1231, 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Public Law 107–295, 116 Stat. 2064; and Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to establish and define regulatory safety zones.

A fireworks display will be taking place on Lake Erie, in the vicinity of Lakeside, OH. The temporary safety zone is necessary to ensure the safety of vessels and spectators from hazards associated with fireworks display. Such hazards include the explosive danger of fireworks and debris falling into the water that may cause death or serious bodily harm. Establishing a safety zone to control vessel movement around the location of the event will help ensure the safety of persons and property at this event and help minimize the associated risks.

C. Discussion of Rule

Because of the aforementioned safety concerns, The Captain of the Port Detroit has determined a temporary safety zone is necessary to ensure the safety of spectators and vessels during the setup, loading, and launching of the Lakeside July 4th Fireworks Display. The Lakeside July 4th Fireworks Display safety zone will encompass all U.S. navigable waters of Sandusky Bay within a 600-foot radius of the fireworks barge located at position 41°32′54″ N., 082°44′52″ W. (NAD 83).

Entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Detroit or his designated on-scene representative. The Captain of the Port or his on-scene representative may be contacted via VHF Channel 16. All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the on-scene representative.

D. Regulatory Analyses

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

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS). We conclude that this rule is not a significant regulatory action because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The safety zone created by this rule will be relatively small and enforced for relatively short time. Also, the safety zone is designed to minimize their impact on navigable waters. Furthermore, restrictions on vessel movement within the area of the safety zone expected to be minimal. Under certain conditions, vessels may still transit through the safety zone when permitted by the Captain of the Port.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which might be small entities: the owners or operators of vessels intending to transit or anchor in designated portions of Lake Erie, OH from 9:30 p.m. through 10:45 p.m. on July 4, 2015.

The safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: The safety zone will be activated, and thus subject to enforcement, for only a short period of time. Traffic may be allowed to pass through the zone with the permission of the Captain of the Port. The Captain of the Port can be reached via VHF channel 16. Before the activation of the zone, we would issue local Broadcast Notice to Mariners.

3. Assistance for Small Entities

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

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

4. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

5. Federalism

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

6. Protest Activities

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

7. Unfunded Mandates Reform Act

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

8. Taking of Private Property

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

9. Civil Justice Reform

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

10. Protection of Children

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

11. Indian Tribal Governments

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

12. Energy Effects

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

13. Technical Standards

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

14. Environment

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T09–0388 to read as follows:

§ 165.T09–0388 Safety Zone; Lakeside July 4th Fireworks, Lake Erie; Lakeside, OH.

(a) *Location.* The following area is a temporary safety zone: Lakeside July 4th Fireworks, all U.S. navigable waters of Lake Erie within a 600-foot radius of the fireworks launch site located at position 41°32′54″ N., 082°44′52″ W. All coordinates are North American Datum 1983 (NAD83).

(b) *Effective and Enforcement Period.* The safety zone will be effective and enforced from 9:30 p.m. through 10:45 p.m. on July 4, 2015.

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

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

(3) The ''on-scene representative'' of the Captain of the Port, Sector Detroit is any Coast Guard commissioned, warrant or petty officer or a Federal, State, or local law enforcement officer designated by or assisting the Captain of the Port, Sector Detroit to act on his behalf.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port, Sector Detroit or his on-scene representative to obtain permission to do so. The Captain of the Port, Sector Detroit or his on-scene representative may be contacted via VHF Channel 16 or at 313–568–9464. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port, Sector Detroit, or his on-scene representative.

Dated: May 14, 2015.

Scott B. Lemasters,

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

[FR Doc. 2015–13159 Filed 5–29–15; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R02–OAR–2014–0683, FRL–9928–39–Region 2]

Approval and Promulgation of Implementation Plans; New York; Infrastructure SIP for the 2008 Lead NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving certain elements of New York's State Implementation Plan (SIP) revision submitted to demonstrate that the State meets the requirements of the Clean Air Act (CAA) for the 2008 National Ambient Air Quality Standard (NAAQS) for lead (Pb). The CAA requires that each state adopt and submit a SIP for the implementation, maintenance and enforcement of each NAAQS promulgated by the EPA and is commonly referred to as an infrastructure SIP.

DATES: This rule is effective on *July 1, 2015.*

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R02–OAR–2014–0683. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Environmental Protection Agency, Region 2 Office, Air Programs Branch, 290 Broadway, 25th Floor, New York, New York 10007–1866. The Air Programs Branch dockets are available from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The Air Programs Branch telephone number is 212–637–4249.

FOR FURTHER INFORMATION CONTACT: Kirk J. Wieber, Air Programs Branch, Environmental Protection Agency, Region 2, 290 Broadway, 25th Floor, New York, New York 10007–1866, (212) 637–4249, or by email at *wieber.kirk@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What is the background information?

On November 12, 2008, EPA promulgated a new, rolling 3 month average NAAQS for Pb, herein referred to as the 2008 Pb NAAQS. See 73 FR 66964.[1] The 2008 Pb NAAQS is 0.15 micrograms per cubic meter of air (μg/m^3) maximum (not-to-be-exceeded). In the same action EPA revised the secondary Pb NAAQS to be identical in all respects to the revised primary standard, *i.e.,* 0.15 μg/m^3.

Section 110(a)(1) provides the procedural and timing requirements for State Implementation Plans (SIPs). Section 110(a)(2) lists specific elements that states must meet for SIP requirements related to a newly established or revised NAAQS. Sections 110(a)(1) and (2) of the CAA require, in part, that states submit to EPA plans to implement, maintain and enforce each of the NAAQS promulgated by EPA. By statute, SIPs meeting the requirements of section 110(a)(1) and (2) are to be submitted by states within three years after promulgation of a new or revised standard. These SIPs are commonly called infrastructure SIPs. Based on the October 15, 2008 date of signature for the 2008 Pb NAAQS, infrastructure SIPs for the 2008 Pb NAAQS were due on October 15, 2011.

EPA is acting on New York's SIP submittal dated October 13, 2011, as supplemented on February 24, 2012, which addresses the section 110 infrastructure requirements for the 2008 Pb NAAQS. Two elements identified in section 110(a)(2) are not governed by the three year submission deadline of section 110(a)(1) because SIPs incorporating necessary local nonattainment area controls are not due within three years after promulgation of a new or revised NAAQS, but rather due at the time that the nonattainment area plan requirements are due pursuant to CAA section 191. (See also CAA section 172 for general nonattainment plan requirements). These requirements are: (1) Submissions required by section 110(a)(2)(C) to the extent that subsection refers to a permit program as required in part D Title I of the CAA, and (2) submissions required by section 110(a)(2)(I) which pertain to the nonattainment planning requirements of part D, Title I of the CAA.

As a result, this action does not address the nonattainment area plan requirements related to section 110(a)(2)(C) or 110(a)(2)(I).

II. What comments did EPA receive in response to its proposal?

On December 15, 2014 (79 FR 74046), EPA proposed to approve New York's SIP submittal addressing the section 110 infrastructure requirements for the 2008 Pb NAAQS. EPA received one adverse comment on the December 15, 2014 proposal. A synopsis of the adverse comment, as well as EPA's response is discussed below.

Comment: EPA must disapprove element C with regard to Prevention of Significant Deterioration (PSD) unless New York has the $PM_{2.5}$ increments approved into its PSD SIP. As you may know, EPA's position is the issue of $PM_{2.5}$ increments is relevant even if this is a lead infrastructure SIP.

Response: Element C requires that each infrastructure SIP contain a permitting program ''as required by part C.'' CAA title I part C is applicable to all pollutants subject to regulation under the CAA. See, *e.g.,* CAA section 165(a)(4). After further review EPA agrees that Element C is not restricted to only those provisions of CAA title I part C that pertain to the particular new or revised NAAQS addressed by the particular infrastructure SIP action. Because the scope of CAA title I part C is comprehensive (covering all pollutants subject to regulation under the CAA, including GHG), the EPA likewise reads the unrestricted reference to CAA title I part C in Element C to mean that this provision has the same scope as CAA title I part C itself. Thus, a fully approved comprehensive PSD program addressing all regulated pollutants is needed in order to approve the infrastructure SIP for any one pollutant.

NYSDEC has adopted and submitted to EPA for approval into its SIP, a PSD program that includes $PM_{2.5}$ increments. However, the $PM_{2.5}$ increments have not yet been approved by EPA. EPA will defer taking final action approving New York's infrastructure SIP submission with respect to the PSD program requirements in sections 110(a)(2)(C), (D)(i)(II) prong 3, and (J) until EPA has approved, or simultaneously approves New York's adopted PSD program.

III. What action is EPA taking?

EPA is approving New York's submittal as fully meeting the infrastructure requirements for the 2008

[1] Final rule signed October 15, 2008. The 1978 lead standard (1.5 μg/m^3 as a quarterly average) remains in effect until one year after an area is designated for the 2008 standard, except that in areas designated nonattainment for the 1978 lead standard, the 1978 standard remains in effect until implementation plans to attain or maintain the 2008 standard are approved.

primary Pb NAAQS for all section 110(a)(2) elements and sub-elements, as follows: (A), (B), (D)(i)(I) prongs 1 and 2, D(i)(II) prong 4, (E), (F), (G), (H), (K), (L), and (M). EPA is not finalizing action on 110(a)(2) elements and sub-elements, as follows: (C), (D)(i)(II) prong 3, and (J). EPA is not acting on New York's submittal as it relates to nonattainment provisions, the NSR program required by part D in section 110(a)(2)(C) and the measures for attainment required by section 110(a)(2)(I), as part of the infrastructure SIPs because the State's infrastructure SIP submittal does not include nonattainment requirements and EPA will act on them when, if necessary, they are submitted.

IV. Statutory and Executive Order Reviews

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive 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).

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

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 31, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Lead, Particulate matter, Reporting and recordkeeping requirements.

Dated: May 8, 2015.

Judith A. Enck,

Regional Administrator, Region 2.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATON PLANS

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

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

Subpart HH—New York

■ 2. In § 52.1670(e), the table titled ''EPA-Approved New York Nonregulatory and Quasi-Regulatory Provisions'' is amended by adding the entry ''Section 110(a)(2) Infrastructure Requirements for the 2008 Primary Pb NAAQS'' at the end of table, to read as follows:

§ 52.1670 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED NEW YORK NONREGULATORY AND QUASI–REGULATORY PROVISIONS

Action/SIP element	Applicable geographic or nonattainment area	New York submittal date	EPA approval date	Explanation
*	*	* *	*	* *
Section 110(a)(2) Infrastructure Requirements for the 2008 Primary Pb NAAQS.	Statewide	10/13/11, and supplemented on 2/24/12.	6/1/15, ... [Insert FR citation]	This action addresses the following CAA elements: 110(a)(2)(A), (B), (D)(i)(I) prongs 1 and 2, D(i)(II) prong 4, (E), (F), (G), (H), (K), (L), and (M).

[FR Doc. 2015–13029 Filed 5–29–15; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2014–0884; FRL–9928–42–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Determination of Attainment of the 2008 8-Hour Ozone National Ambient Air Quality Standard for the Baltimore, Maryland Moderate Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is making the determination that the Baltimore, Maryland Moderate Nonattainment Area (Baltimore Area) has attained the 2008 8-hour ozone National Ambient Air Quality Standard (NAAQS). This determination is based upon complete, quality-assured, and certified ambient air quality monitoring data that shows the Baltimore Area has monitored attainment of the 2008 8-hour ozone NAAQS for the 2012–2014 monitoring period. As a result of this determination, the requirement for the Baltimore Area to submit an attainment demonstration and associated reasonably available control measures (RACM), reasonable further progress plans (RFP), contingency measures, and other State Implementation Plan (SIP) revisions related to attainment of the standard are suspended for as long as the area continues to attain the 2008 8-hour ozone standard.

DATES: This final rule is effective on July 1, 2015.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2014–0884. All documents in the docket are listed in the www.regulations.gov Web site. Although listed in the electronic docket, some information is not publicly available, *i.e.,* confidential business information (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 through *www.regulations.gov* or in hard copy for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

FOR FURTHER INFORMATION CONTACT: Irene Shandruk, (215) 814–2166, or by email at *shandruk.irene@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On March 12, 2008, EPA revised both the primary and secondary NAAQS for ozone to a level of 0.075 parts per million (ppm) (annual fourth-highest daily maximum 8-hour average concentration, averaged over three years) to provide increased protection of public health and the environment. 73 FR 16436 (March 27, 2008).[1] The 2008 ozone NAAQS retains the same general form and averaging time as the 0.08 ppm NAAQS set in 1997, but is set at a more protective level. On May 21, 2012 (77 FR 30088), effective July 20, 2012, EPA designated as nonattainment any area that was violating the 2008 8-hour ozone NAAQS based on the three most recent years (2008–2010) of air monitoring data. The Baltimore Area (specifically, Anne Arundel County, Baltimore City, Baltimore County, Carroll County, Harford County, and Howard County) was designated as a moderate ozone nonattainment area. *See* 40 CFR 81.321. Moderate areas are required to attain the 2008 8-hour ozone NAAQS by no later than six years after the effective date of designations, or July 20, 2018. *See* 40 CFR 51.903. Air quality monitoring data from the 2012–2014 monitoring period indicate that the Baltimore Area is now attaining the 2008 8-hour ozone NAAQS. On March 18, 2015 (80 FR 14041), EPA published a notice of proposed rulemaking (NPR), which proposed to determine that the Baltimore Area has attained the 2008 8-hour ozone NAAQS. Public comments were received on the NPR. Summaries of the comments as well as EPA's responses are in section III of this rulemaking notice.

Under the provisions of 40 CFR 51.1118,[2] also known as EPA's Clean Data Policy, a determination by EPA that an area is attaining the relevant standard (through a rulemaking that includes public notice and comment) suspends the area's obligations to submit an attainment demonstration, RACM, RFP, contingency measures and other planning requirements related to attainment of the 2008 8-hour ozone NAAQS for as long as the area continues to attain the standard. This suspension remains in effect until such time, if ever, that EPA (i) redesignates the area to attainment at which time those requirements no longer apply, or (ii) subsequently determines that the area has violated the 2008 8-hour ozone NAAQS. Although these requirements are suspended, EPA remains obligated under section 110(k)(2) to act upon these elements at any time if submitted to EPA for review and approval. On April 22, 2015, the Maryland Department of the Environment (MDE) sent correspondence to EPA indicating its intent to submit an attainment SIP for the 2008 8-hour ozone NAAQS.[3] This determination of attainment is not equivalent to a redesignation under section 107(d)(3) of the CAA. The designation status of the Baltimore Area will remain nonattainment for the 2008 8-hour ozone NAAQS until such time as EPA determines that the Area meets the Clean Air Act (CAA) requirements for redesignation to attainment, including an approved maintenance plan. Additionally, the determination of attainment is separate from, and does not influence or otherwise affect, any future designation determination or requirements for the Baltimore Area based on any new or revised ozone NAAQS, and it remains in effect regardless of whether EPA designates this Area as a nonattainment area for purposes of any new or revised ozone NAAQS. Finally, this determination does not relieve other CAA requirements that are not related to attainment planning and achievement of the NAAQS, such as an emissions inventory as required by CAA section 172(c)(3) or a nonattainment area permitting program pursuant to CAA sections 172(c)(5) and 173.

II. EPA's Evaluation

EPA has reviewed the complete, quality-assured and certified ozone ambient air monitoring data for the monitoring period for 2012–2014 for the Baltimore Area. The design values for each monitor for the years 2012–2014 are less than or equal to 0.075 ppm which is the 2008 ozone NAAQS level, and all monitors meet the data completeness requirements (*see* Table

[1] For a detailed explanation of the calculation of the 3-year 8-hour average, see 40 CFR part 50, Appendix I.

[2] EPA issued its proposal to determine that the Baltimore Area was attaining the 2008 ozone NAAQS pursuant to 40 CFR 51.918, EPA's Clean Data Policy under the 1997 8-hour ozone implementation rule. On April 6, 2015, EPA's plan implementing the 2008 ozone NAAQS became effective, thereby replacing 40 CFR 51.918 with 40 CFR 51.1118, a functionally identical provision for purposes of this action. *See* 40 CFR 51.919.

[3] The April 22, 2015 letter from MDE is available in the docket for this rulemaking under docket number EPA–R03–OAR–2014–0884.

1).[4] Based on this 2012–2014 data from EPA's Air Quality System (AQS) database and consistent with the requirements contained in 40 CFR part 50, EPA has concluded that this Area attained the 2008 8-hour ozone NAAQS.

TABLE 1—2012–2014 BALTIMORE AREA 2008 8-HOUR OZONE DESIGN VALUES

Monitor ID	Average percent data completeness	2012–2014 Design value (ppm)
24–003–0014	97	0.074
24–005–1007	95	0.072
24–005–3001	99	0.072
24–013–0001	99	0.069
24–025–1001	98	0.075
24–025–9001	96	0.073
24–510–0054	90	0.064

The data in Table 1 are available in EPA's AQS database. The AQS report with this data is available in the docket for this rulemaking under docket number EPA–R03–OAR–2014–0884 and available online at *www.regulations.gov*, docket number EPA–R03–OAR–2014–0884. Other specific requirements of the determination and the rationale for EPA's proposed action were explained in the NPR and will not be restated here.

III. Summary of Public Comments and EPA Responses

EPA received the following adverse comments on the proposed determination of attainment for the Baltimore Area for the 2008 8-hour ozone NAAQS. A summary of the adverse comments and our responses follow.

Comment 1: A commenter stated that EPA's proposed determination of attainment for the 2008 8-hour ozone standard for the Baltimore Area thwarts the CAA's mandate of expeditious attainment of the NAAQS because the monitored data are the result of unusual weather patterns resulting in low ozone concentrations in Baltimore's air quality, which the commenter asserts is likely to revert back to monitored nonattainment in the near future. The commenter further states that this is of particular concern in the Baltimore Area given that asthma is an endemic problem and an environmental justice issue in Maryland. According to the commenter, issuance of a determination of attainment for the Baltimore Area for the 8-hour ozone NAAQS would defer additional needed air quality planning requirements, delay permanent attainment, and jeopardize public health. The commenter also asserts Maryland cannot rely on voluntary control measures which are not permanent and enforceable. Therefore, the commenter stated EPA's issuance of the determination of attainment would be arbitrary, capricious and counterproductive to the mandate of the CAA.

Response 1: EPA disagrees with the commenter that EPA should not finalize the determination of attainment because, in accordance with EPA regulations and longstanding policy for such determinations, and in accordance with the intent of the CAA, the area is factually attaining the NAAQS. As the commenter acknowledges, unlike the CAA's redesignation requirement that an area's attainment air quality is due to permanent and enforceable measures in CAA section 7407(d)(3)(E)(iii), EPA's Clean Data Policy does not require an analogous demonstration. *See* 40 CFR 51.1118. It is for this reason that EPA's determination of attainment merely suspends the requirement to submit attainment planning SIPs for only so long as the area continues to attain the standard. If the area falls back into nonattainment, those attainment planning SIPs become immediately due upon a determination by EPA that the area is no longer attaining the NAAQS. Moreover, Maryland may still submit SIPs in anticipation of this event, and EPA will be required to act on those SIPs in accordance with CAA section 7410(k)(2) and (3). The Clean Data Policy embodies EPA's longstanding interpretation that certain planning requirements in the CAA no longer have meaning for areas that are attaining the standard because the purpose of these provisions is to help a nonattainment area reach attainment, a goal which will already have been achieved.

Following enactment of the CAA Amendments of 1990, EPA promulgated its interpretation of the requirements for implementing the NAAQS in the general preamble for the implementation of Title I of the CAA Amendments of 1990 (General Preamble). *See* 57 FR 13498, 13564 (April 16, 1992). In 1995, based on the interpretation of CAA sections 171, 172, and 182 in the General Preamble, EPA set forth what has become known as its ''Clean Data Policy'' for the 1-hour ozone NAAQS. *See* Reasonable Further Progress, Attainment Demonstration, and Related Requirements for Ozone Nonattainment Areas Meeting the Ozone National Ambient Air Quality Standard, EPA memorandum from John S. Seitz, Director, Office of Air Quality Planning Standards, May 10, 1995 (Seitz Memorandum). The Seitz Memorandum provided that requirements to submit SIP revisions addressing RFP, an attainment demonstration, and other related requirements such as contingency measures and other specific ozone-related requirements in section 182 would be suspended for as long as the nonattainment area continued to monitor attainment of the NAAQS. EPA incorporated its ''Clean Data Policy'' interpretation in both its 8-Hour Ozone Implementation Rule in 40 CFR 51.918, its Final Clean Air Fine Particle Implementation Rule (1997 $PM_{2.5}$ Implementation Rule) in 40 CFR 51.1004(c), the SIP requirements rule for the 2008 ozone NAAQS published on March 6, 2015 (80 FR 12264), and the proposed PM implementation rule published on March 23, 2015 (80 FR 15340). *See* 72 FR 20585, 20665 (April

[4] Under EPA regulations at 40 CFR part 50, the 2008 8-hour ozone NAAQS is attained when the 3-year average of the annual fourth-highest daily maximum 8-hour average ozone concentrations at an ozone monitor is less than or equal to 0.075 ppm. *See* 40 CFR part 50, Appendix P. This 3-year average is referred to as the design value. When the design value is less than or equal to 0.075 ppm at each monitor within the area, then the area is attaining the NAAQS. The data completeness requirement is met when the average percent of days with valid ambient monitoring data is greater than or equal to 90 percent (%), and no single year has less than 75% data completeness as determined in Appendix P of 40 CFR part 50. The data must be collected and quality-assured in accordance with 40 CFR part 58, and recorded in EPA's Air Quality System.

25, 2007).[5] Over the past two decades, in regulations, guidance memoranda, and numerous individual rulemakings, EPA has consistently articulated its Clean Data Policy interpretation as applying to the attainment-related SIP planning provisions of subparts 1, 2 and 4 of Part D of Title I of the CAA, and the spectrum of ambient air quality standards, including the 1-hour and 1997 ozone, coarse particulate matter (PM_{10}), fine particulate matter ($PM_{2.5}$), and lead (Pb) NAAQS. *See e.g.* 79 FR 77911 (December 29, 2014) (determination of attainment of 2008 Pb NAAQS); 79 FR 25014 (May 2, 2014) (determination of attainment of 2006 $PM_{2.5}$ NAAQS); 79 FR 21139 (April 15, 2014) (determination of attainment of 2008 ozone NAAQS); 78 FR 20244 (April 4, 2013) (determination of attainment of 1997 ozone NAAQS); and 77 FR 36163 (June 18, 2012) (determination of attainment of 1-hour ozone NAAQS). The D.C. Circuit explicitly upheld EPA's Clean Data Policy interpretation as embodied in the1997 8-Hour Ozone Implementation Rule, 40 CFR 51.918.[6] *NRDC* v. *EPA,* 571 F. 3d 1245, 1258–61 (D.C. Cir. 2009). Other U.S. Circuit Courts of Appeals that have considered and reviewed EPA's Clean Data Policy interpretation have similarly upheld it and the rulemakings applying EPA's interpretation. *Sierra Club* v. *EPA,* 99 F.3d 1551 (10th Cir. 1996); *Our Children's Earth Foundation* v. *EPA,* N. 04–73032 (9th Cir. June 28, 2005) (memorandum opinion); and *Latino Issues Forum* v. *EPA,* Nos. 06–75831 and 08–71238 (9th Cir. March 2, 2009) (memorandum opinion).

Because EPA finds the Baltimore Area's monitoring data supports a determination that the Baltimore Area has attained the 2008 ozone NAAQS as explained above and in the NPR, EPA disagrees with the commenter that EPA should not issue at this time a determination of attainment which suspends SIP planning requirements for the Baltimore Area pursuant to our Clean Data Policy. EPA acts to protect the public health in accordance with the CAA and its mandates and the Agency is concerned with increased asthma incidences as well as with ensuring environmental justice for communities. EPA's determination of attainment for the Baltimore Area is in accordance with our regulations and longstanding policy and is based on monitored ozone data demonstrating attainment with the 2008 8-hour ozone NAAQS, which EPA set at a level to protect the public health. Thus, EPA's action is in accordance with the CAA, its implementing regulations, and policy.

Second, to the extent that the commenter is suggesting that EPA may not issue a determination of attainment where the factors that contributed to attainment are not permanent, EPA notes that such a requirement is a prerequisite to a redesignation of a nonattainment area under CAA section 107(d)(3)(E)(iii), but not for a determination of attainment. A redesignation changes the legal status of an area from nonattainment of the NAAQS to attainment of the NAAQS, and is not pertinent to determinations of attainment that simply suspend attainment planning requirements in Part D of Title I of the CAA. Thus, EPA disagrees with the commenter that our determination of attainment, which is based on data from ozone monitors in the Baltimore Area showing attainment with the 2008 ozone NAAQS in accordance with 40 CFR part 50, Appendix P, is arbitrary or capricious, or contrary to the CAA.

Finally, under the provisions of EPA's ozone implementation rules (40 CFR 51.918 and 51.919), if EPA issues a determination that an area is attaining the relevant standard (through a rulemaking that includes public notice and comment), it will suspend the area's obligations to submit an attainment demonstration, RACM, RFP, contingency measures and other planning requirements related to attainment of the 2008 8-hour ozone NAAQS for as long as the area continues to attain the standard. This suspension remains in effect until such time, if ever, that EPA (i) redesignates the area to attainment at which time those requirements no longer apply, or (ii) subsequently determines that the area has violated the 2008 8-hour ozone NAAQS. Although these requirements are suspended, EPA is required to act upon these elements if submitted to EPA for review and approval. In fact, Maryland has stated its intent to submit an attainment plan for the 2008 8-hour ozone NAAQS, which will address SIP attainment planning requirements in sections 172 and 182 of the CAA, including control measures, RACM, RFP and contingency measures which will assist the Baltimore Area with maintenance of the NAAQS. *See* April 22, 2015 letter from MDE to EPA regarding plans for 2008 ozone NAAQS attainment SIP which is included in the docket for this rulemaking action. Thus, EPA has considered the commenter's concern that this rulemaking will delay attainment planning which could assist with maintenance with the NAAQS, and has determined that MDE is addressing these concerns. Furthermore, EPA's NPR which proposed to determine the Baltimore Area had attained the 2008 8-hour ozone NAAQS has not delayed or interfered with MDE's plans for additional control measures to address ozone formation and attainment and maintenance of ozone NAAQS. For example, MDE recently proposed action on new nitrogen oxide (NO_X) regulations for electric generating units (EGUs), which may assist the Area with maintenance of the 2008 8-hour ozone NAAQS.[7] *See* COMAR 26.11.38 (proposed April 17, 2015).[8] In addition, EPA expects further NO_X reductions will occur in Maryland with the projected closure of coal-fired power generating units at NRG Energy's Dickerson and Chalk Point power plants which are projected to deactivate by 2018.[9] In addition, many other coal-fired EGUs in Maryland and in states neighboring Maryland have already deactivated or will soon deactivate in 2015 and 2016, including R. Paul Smith, Potomac River, Chesapeake, Clinch River, Glen Lynn, Armstrong, Elrama, Hatfields Ferry, Mitchell, Willow Island, Albright, Kammer, Kanawha River, Phillip Sporn, Rivesville, Walter C. Beckjord, Muskingum River, Eastlake, Ashtabula, and Big Sandy, which will likely result in further NO_X and ozone

[5] While the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) in a January 4, 2013 decision remanded the 1997 $PM_{2.5}$ Implementation Rule to EPA, the D.C. Circuit did not address the merits of that regulation regarding our Clean Data Policy in 40 CFR 51.1004(c), nor cast any doubt on EPA's existing interpretation of the statutory provisions for the Clean Data Policy. *See Natural Resources Defense Council* v. *EPA,* 706 F.3d 428 (D.C. Cir. 2013).

[6] ''EPA's Final Rule to implement the 8-Hour Ozone National Ambient Air Quality Standard-Phase 2 (Phase 2 Final Rule).'' *See* 70 FR 71612, 71645–46 (November 29, 2005).

[7] NO_X is a precursor pollutant which reacts in the atmosphere to form ozone.

[8] According to MDE's Web site, MDE has petitioned the Administrative, Executive, and Legislative Review (AELR) Committee of the Maryland General Assembly requesting emergency status for COMAR 26.11.38. If the AELR Committee grants its approval, the emergency measure for NO_X reductions at EGUs may go into effect immediately. To become a permanent regulation, the regulation must be promulgated following the State required administrative procedures, which includes a 30-day public comment period. *See http://www.mde.state.md.us/programs/regulations/air/Pages/Emergency.aspx.* For additional information including the proposed regulations, *see http://www.mde.state.md.us/programs/regulations/air/Documents/COMAR_26.11.38.pdf* and *http://www.baltimoresun.com/news/maryland/bs-md-air-pollution-rule-20150417-story.html.*

[9] For a listing of EGUs which deactivated already or are planning to deactivate in the states which are part of PJM Interconnection, L.L.C., a regional transmission organization which coordinates the movement of wholesale electricity within states including Maryland, see *http://www.pjm.com/planning/generation-deactivation/gd-summaries.aspx.*

reductions and thereby additionally address the commenter's concerns with continued attainment and maintenance of the ozone NAAQS in the Baltimore Area.[10]

Comment 2: The commenter asserts that EPA should not issue a determination of attainment for the Baltimore Area because the Area experienced atypical weather conditions in 2013 and 2014, leading to lower monitored ozone levels in the Area, and asserts the Area is likely to revert back to nonattainment in the near future. The commenter states that unusually cool summers, increased precipitation, and shifting ozone transport patterns which occurred in 2013 and 2014 contributed to unusually low ozone levels in the Baltimore Area, but that the National Oceanic Atmospheric Administration (NOAA) predicts that such aberrant weather trends will not continue through summer 2015. The commenter asserts the Baltimore Area could revert to nonattainment if summers are warmer with less precipitation than 2013 and 2014. The commenter cites to statements from Maryland and the Ozone Transport Commission regarding the shifting weather and transport patterns in 2013 and 2014.[11] Furthermore, the commenter asserts that 2013 and 2014 atypical weather conditions led to lower energy demand due to less use of air conditioners by consumers in summer, and thereby led to lower coal plant operations, and presumably lower NO_X emissions helping to keep ozone levels low. The commenter notes the coal-fired EGUs in Maryland have generally operated less in recent years but tend to continue to operate on warmer summer days, which the commenter says are the most ''sensitive'' from the ozone and public health perspective. Thus, the commenter states EPA should decline to issue the clean data determination for the Baltimore Area because of the aberrant weather in 2013 and 2014 and because the Area is likely to revert back to nonattainment in the near future.

Response 2: EPA disagrees with the commenter that transport of NO_X or ozone or that weather patterns including unusual patterns of transport of pollution and cooler, wetter weather data than historical averages should impact EPA's determination of attainment for the Baltimore Area with respect to the 2008 8-hour ozone NAAQS. EPA's determinations of attainment with a NAAQS are based entirely on monitoring data and on our evaluation of that data's compliance with 40 CFR part 50, Appendix P. Therefore, weather conditions, transport patterns, energy demand, and EGU megawatt generation that the commenter alleges may impact NO_X and ozone pollution levels are irrelevant in determining whether an area is attaining a NAAQS. Under EPA regulations at 40 CFR part 50, the 2008 8-hour ozone NAAQS is attained when the 3-year average of the annual fourth-highest daily maximum 8-hour average ozone concentrations at an ozone monitor is less than or equal to 0.075 ppm. *See* 40 CFR part 50, Appendix P. This 3-year average is the design value. When the design value is less than or equal to 0.075 ppm at each monitor within the area, then the area is attaining the NAAQS. EPA's analysis of monitoring data in the Baltimore Area (included in Section II of this rulemaking action) supports the determination that the Baltimore Area has attained the 2008 8-hour ozone NAAQS. In addition, the data completeness requirement for evaluating monitoring data for NAAQS attainment is met when the average percent of days with valid ambient monitoring data is greater than or equal to 90 percent (%), and no single year has less than 75% data completeness as defined in Appendix P of 40 CFR part 50. Monitor data must also be collected and quality-assured in accordance with 40 CFR part 58 and recorded in the EPA's AQS. EPA's analysis in Section II of this rulemaking action of the monitor data in the Baltimore Area shows the Baltimore Area monitors meet the completeness criterion which also supports our determination that the Baltimore Area has attained the 2008 8-hour ozone NAAQS.

In sum, EPA reviewed the complete, quality-assured and certified ozone ambient air monitoring data for the 2012–2014 monitoring period for the Baltimore Area. The design values for each monitor for the years 2012–2014 are less than or equal to 0.075 ppm, and all monitors meet the data completeness requirements (*see* Table 1 in Section II of this rulemaking action). Thus, EPA disagrees with the commenter that EPA should not issue the determination of attainment based on factors such as atypical weather, transport, or reduced EGU generation. The Baltimore Area has attained the 2008 8-hour ozone NAAQS in accordance with 40 CFR part 50, Appendix P requirements and 40 CFR 51.918. Thus, EPA's determination is in accordance with CAA requirements and is not arbitrary or capricious.[12] If the Baltimore Area's monitors show design values exceeding the 2008 8-hour ozone NAAQS in the future, EPA will take appropriate action to remove the suspension of attainment plan requirements as discussed in this rulemaking and in the NPR. Furthermore, as noted in response to Comment 1, notwithstanding the lawful suspension of these requirements in accordance with 40 CFR 51.1118, the state has indicated that it plans to continue working on submissions to address the suspended attainment planning requirements, which EPA will be required to act upon in accordance with CAA section 110(k).

Comment 3: The commenter states that Baltimore's ozone monitors do not accurately capture all maximum ozone exposures. According to the commenter, several ozone monitors in the Baltimore Area (including specifically the Davidsonville, Padonia, and Aldino monitors) have shut off for several days during the ozone season in 2011, 2012 and 2013, and on several occasions, shut off on very hot days as ozone concentrations increased. The commenter asserts these monitors may have missed exceedances that would have kept the monitor in nonattainment for 2012–2014 with the 2008 8-hour ozone NAAQS. The commenter states the untimely shut-offs of ozone monitors call into question the ''cleanliness'' of the Area's data as monitors were ''down and failing to record ambient ozone levels at critical points during ozone season and summer heat waves.'' The commenter states EPA should decline to grant the clean data determination at this time due to ''illusory air quality improvements.'' Because the commenter questions the monitoring data due to certain shut off episodes, the commenter additionally claims EPA's determination of attainment for the Baltimore Area is arbitrary, capricious and contrary to law.

Response 3: EPA disagrees with the commenter that EPA should not finalize

[10] *See http://www.pjm.com/planning/generation-deactivation/gd-summaries.aspx.*

[11] By reference to ''transport,'' the commenter refers to the transport of air pollution and pollutants from upwind states to downwind states in the atmosphere.

[12] EPA also discussed the irrelevance of atypical weather in EPA's approval of the attainment demonstration for the Washington DC–MD–VA, moderate ozone nonattainment area for the 1997 ozone NAAQS. 80 FR 19206 (April 10, 2015). In response to comments that the weather in 2012 was cooler and wetter than average which led to ozone levels lower than seen in prior years, EPA agreed that weather plays an important role in ozone formation but stated that these considerations do not require EPA to disapprove the attainment demonstration where modeling and actual design values from ambient air quality monitors demonstrated attainment of the NAAQS. *Id.* at 19213–214 (stating EPA's approval of attainment demonstration was in accordance with CAA statutory requirements).

this determination of attainment for the Baltimore Area for the 2008 8-hour ozone NAAQS due to concerns raised by the commenter with respect to certain ozone monitors in the Area, and disagrees that EPA's determination is arbitrary, capricious or contrary to law. As discussed previously, EPA issues determinations of attainment for the NAAQS based solely on monitoring data input into EPA's AQS demonstrating attainment with a NAAQS in accordance with requirements for attainment in 40 CFR part 50, Appendix P, regardless of weather or transport conditions or patterns. For EPA to issue a determination of attainment, one important criterion is that the monitoring data must meet the completeness requirements set forth in Appendix P of 40 CFR part 50 (amongst other requirements.) The data completeness requirement is met when the average percent of days with valid ambient monitoring data is greater than or equal to 90%, and no single year has less than 75% data completeness. EPA has determined that the 2012–2014 ozone monitoring data in the Baltimore Area meet these requirements because the average percent of days with valid ambient monitoring data is greater than or equal to 90% and because no single year has less than 75% data completeness. Therefore, EPA has sufficient data in accordance with Appendix P of 40 CFR part 50 for issuance of the determination of attainment for the Baltimore Area with the 2008 8-hour ozone NAAQS. EPA disagrees with the commenter that the monitors ''shutting off'' create illusory air quality improvements as the monitors satisfy EPA's data completeness requirements.

In addition, EPA disagrees with the commenter's characterization that the monitors were ''shutting off,'' and EPA finds it unreasonable to infer ozone exceedances may have occurred during any periods when monitors may not have collected valid data. Ozone monitors are sophisticated analytical instruments. While they mostly operate quite reliably, there may be occasional incidences where monitors malfunction or produce erroneous or compromised data despite best efforts at maintenance and good operating practices. EPA believes it is unreasonable to expect any ozone monitor to operate continuously twenty-four hours a day for seven days a week over the seven month ozone season without experiencing any operational issues. EPA believes routine issues may be expected to occur affecting monitor operation and performance including issues such as ultraviolet lamps and vacuum pumps needing repair, particulate filters becoming clogged, and water vapor condensing in the sample manifold and being drawn into the monitor.

In addition, monitors must be operated in environmentally controlled buildings or instrument shelters. If the air conditioning fails and the monitors overheat, unstable readings may occur. If the temperature gets too cold in a shelter on a hot and humid day, condensation can occur and affect the ozone readings. Condensation may also impact a monitor because ozone exceedance days are often observed on warm and humid days. Further, monitoring stations frequently house additional monitoring equipment creating a high electrical demand. Thus, monitors are susceptible to electrical power disturbances from power failures due to stress on the electrical grid or from power failures due to thunderstorms which also frequently occur during hot and humid ozone exceedance days.

To combat such issues, a strict schedule of preventative maintenance, operational checks, daily zero and span challenges, periodic audits and a minimum of bi-weekly precision checks are in place by state agencies operating monitors such as MDE to insure that any monitor problems are addressed in a timely manner and that the highest possible quality data is being produced. Since MDE produces daily ozone forecasts, MDE's monitoring site operators are alerted ahead of time when they can expect ozone exceedance days and extra efforts are taken to insure that the monitors are operating properly as practically possible.

Because of these concerns with monitor operations, Appendix P of 40 CFR part 50 accounts for potential missing data with the completeness criterion discussed previously. All of the Baltimore Area ozone monitors meet these requirements for the period in question. EPA reviewed data from the Davidsonville, Padonia, and Aldino monitors noted by the commenter as having missing data from 2011–2013 including on hotter days in the ozone season. In general, EPA believes that the characterization of these monitors as being ''shut off'' is not accurate. Instead, EPA found the data from these monitors was invalidated for very brief periods or was briefly not collected due to operational concerns such as malfunctioning air conditioning units, power failures, and condensation concerns in sample lines. EPA's analysis of the Davidsonville, Padonia, and Aldino monitors for the time periods noted by the commenter is included in a Supplemental Technical Support Document (Supplemental TSD) which is available in the docket for this rulemaking action under Docket ID Number EPA–R03–OAR–2014–0884. EPA also believes it is unlikely that the monitors missed high ozone exceedances as other monitors were operating in or near the Baltimore Area during some of these limited occasions and were not reporting exceedances. EPA finds it is unreasonable for the commenter to infer ozone exceedances would have occurred during the very limited periods of invalidated data or uncollected data due to power outages because ozone concentrations are not solely dependent on temperature, because ozone concentrations do not behave linearly from day to day at each monitor, and because such inference ignores the meteorology and the behavior of the other ozone monitors in Maryland, which did not report exceedances on the same days and times when these three monitors had limited periods of invalidated data.[13] For a detailed discussion of monitor performance and an explanation for the brief periods of invalidated data at each of the noted monitors, see the Supplemental TSD.

In conclusion, because EPA's determination of attainment for the Baltimore Area is in accordance with established CAA requirements and is supported by EPA analysis in the NPR and in Section II of this rulemaking action regarding complete, quality-assured, and certified ambient air monitoring data that shows the Baltimore Area has monitored attainment of the 2008 8-hour ozone NAAQS for the 2012–2014 monitoring period, EPA's determination is neither arbitrary, capricious, nor contrary to the CAA.

IV. Final Action

EPA has determined that the Baltimore Area has attained the 2008 8-hour ozone NAAQS. This determination is based upon complete, quality-assured, and certified ambient air monitoring data that show the Baltimore Area has monitored attainment of the 2008 8-hour ozone NAAQS for the

[13] For example, one period of unavailable monitor data noted by the commenter around June 29, 2012 at the Davidsonville monitor occurred due to a power failure brought on by a historic storm (known as a derecho) which caused extensive power outages and property damage in Maryland. Despite the summer heat, none of the other Baltimore area monitors registered exceedances during that period of time as temperature is not always directly linked to ozone exceedances. EPA finds it reasonable during this derecho that strong winds likely swept ozone away from the Area based on monitoring data from nearby monitors.

2012–2014 monitoring period. This determination suspends the requirement for Maryland to submit an attainment demonstration for the Baltimore Area, RACM, a RFP plan, contingency measures, and other planning requirements related to attainment of the 2008 8-hour ozone NAAQS for so long as the Baltimore Area continues to attain the 2008 8-hour ozone NAAQS. Although these requirements are suspended, EPA is still obligated to act upon revisions addressing these requirements if submitted to EPA for review and approval. Finalizing this determination does not constitute a redesignation of the Baltimore Area to attainment for the 2008 8-hour ozone NAAQS under CAA section 107(d)(3). Therefore, the designation status of the Baltimore Area will remain nonattainment for the 2008 8-hour ozone NAAQS until such time as EPA takes final rulemaking action to determine that the Baltimore Area meets the CAA requirements for redesignation to attainment. Finally, this determination does not relieve other CAA requirements that are not related to attainment planning and achievement of the NAAQS such as an emissions inventory as required by CAA section 172(c)(3) or a nonattainment area permitting program pursuant to CAA sections 172(c)(5) and 173.

V. Statutory and Executive Order Reviews

A. General Requirements

This action makes a determination of attainment based on air quality, and will result in the suspension of certain Federal requirements, and will 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 se.*);
- 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 se.*);
- 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 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.

B. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et se.,* 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).

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 31, 2015. 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 determining that the Baltimore Area has attained the 2008 8-hour ozone NAAQS may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: May 19, 2015.

William C. Early,

Acting Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart V—Maryland

■ 2. In § 52.1082, paragraph (i) is added to read as follows:

§ 52.1082 Determinations of attainment.

* * * * *

(i) EPA has determined, as of *June 1, 2015,* that based on 2012 to 2014 ambient air quality data, the Baltimore nonattainment area has attained the 2008 8-hour ozone NAAQS. This determination, in accordance with 40 CFR 51.1118, suspends the requirement for this area to submit an attainment demonstration, associated reasonably available control measures, a reasonable further progress plan, contingency measures, and other planning SIPs related to attainment of the standard for as long as this area continues to meet the 2008 8-hour ozone NAAQS.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 141107936–5399–02]

RIN 0648–BE55

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Snapper-Grouper Fishery Off the Southern Atlantic States; Amendment 29

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

ACTION: Final rule.

SUMMARY: NMFS issues this final rule to implement Amendment 29 to the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP) (Amendment 29), as prepared and submitted by the South Atlantic Fishery Management Council (Council). Amendment 29 and this final rule revise annual catch limits (ACLs) and recreational annual catch targets (ACTs) for four unassessed snapper-grouper species and three snapper-grouper species complexes based on an update to the acceptable biological catch (ABC) control rule and revised ABCs for 14 snapper-grouper stocks. Additionally, this final rule revises management measures for gray triggerfish in Federal waters in the South Atlantic region, including modifying minimum size limits, establishing a split commercial season, and establishing a commercial trip limit. The purpose of this final rule is to revise ACLs for select snapper-grouper species using the best scientific information available, and to address concerns about inconsistent minimum size limits among states, and early harvest closures in the commercial sector for gray triggerfish.

DATES: This rule is effective July 1, 2015.

ADDRESSES: Electronic copies of Amendment 29, which includes an environmental assessment (EA), a Regulatory Flexibility Act (RFA) analysis, and a regulatory impact review, may be obtained from the Southeast Regional Office Web site at *http://sero.nmfs.noaa.gov/sustainable_fisheries/s_atl/sg.*

FOR FURTHER INFORMATION CONTACT: Karla Gore, telephone: 727–824–5305, or email: *karla.gore@noaa.gov.*

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery of the South Atlantic 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 November 24, 2014, NMFS published a notice of availability for Amendment 29 and requested public comment through January 23, 2015 (79 FR 69819). On December 8, 2014, NMFS published a proposed rule for Amendment 29 and requested public comment through January 7, 2015 (79 FR 72567). NMFS approved Amendment 29 on February 20, 2015. The proposed rule and Amendment 29 set forth the rationale for the actions contained in this final rule. A summary of the actions implemented by Amendment 29 and this final rule is provided below.

Management Measures Contained in Amendment 29 and This Final Rule

Amendment 29 updates the ABC control rule for unassessed stocks, revises the ABCs for 14 snapper-grouper species through application of the new control rule, and revises the recreational ACTs for three snapper-grouper species complexes and four snapper-grouper species based on the revised ABCs. Amendment 29 and this final rule revise the ACLs for the commercial and recreational sectors for three snapper-grouper species complexes and four snapper-grouper species based on the revised ABCs, and for gray triggerfish, modify the minimum size limits, and establish a split commercial fishing season and a commercial trip limit.

Amendment 29 Updates the ABC Control Rule

Amendment 29 modifies the ABC control rule to use the Only Reliable Catch Stocks (ORCS) approach, recommended by the Council's Scientific and Statistical Committee (SSC), which is a method for calculating ABC values for unassessed stocks when there is only reliable catch information available. Amendment 29 describes the ORCS approach in detail. Amendment 29 employs the ORCS approach to revise ABC values for the following unassessed snapper-grouper species: Bar jack, margate, red hind, cubera snapper, yellowedge grouper, silk snapper, Atlantic spadefish, gray snapper, lane snapper, rock hind, tomtate, white grunt, scamp, and gray triggerfish.

Revise Annual Catch Limits for Select Species

Amendment 29 and this final rule revise the ACLs for the commercial and recreational sectors for three snapper-grouper species complexes and four snapper-grouper species based on the revised ABCs using the ORCS approach, and set the ACL and optimum yield (OY) equal to the ABC for the snappers complex, grunts complex, shallow-water complex, bar jack, Atlantic spadefish, and gray triggerfish. For scamp, the ACL and OY equal 90 percent of the ABC, due to concerns about stock status.

Modify Minimum Size Limit for Gray Triggerfish

Amendment 29 and this final rule establish a 12-inch (30.5-cm), fork length (FL), minimum size limit for gray triggerfish in Federal waters off North Carolina, South Carolina, and Georgia for both the commercial and recreational sectors and increase the minimum size limit to 14 inches (35.6 cm) FL off the east coast of Florida for both the commercial and recreational sectors.

Establish a Split Commercial Season for Gray Triggerfish

Amendment 29 and this final rule divide the annual commercial fishing season for gray triggerfish into two 6-month fishing seasons and allocate 50 percent of the 312,324 lb (141,668 kg) commercial gray triggerfish ACL, or 156,162 lb (70,834 kg), round weight, to each fishing season, January 1 through June 30, and July 1 through December 31. When the quota is reached during either fishing season, the commercial sector closes. In addition, any unused portion of the quota from the first fishing season is added to the quota in the second season. Any unused portion of the quota specified in the second fishing season, including any addition of quota from the first season, becomes void and is not added to any subsequent quota. Because this final rule is being implemented halfway through the 2015 fishing year and commercial landings of gray triggerfish have accumulated, the quota for the 2015 July 1 through December 31 fishing season will be the difference between the new total commercial ACL of 312,324 lb (141,668 kg) and the amount of commercial landings that have occurred by July 1, 2015.

Establish a Commercial Trip Limit for Gray Triggerfish

Amendment 29 and this final rule establish a commercial trip limit of 1,000 lb (454 kg), round weight, for gray triggerfish.

Comments and Responses

NMFS received a total of 15 comment letters from the public during the

comment period on Amendment 29 and the proposed rule. Of these, seven expressed opposition and one expressed support for actions in Amendment 29. The remaining letters were unrelated to the actions proposed in the amendment. The comments related to Amendment 29 and NMFS's respective responses are summarized below.

Comment 1: The ORCS approach is not based on the best available scientific information because it diverges from the recommendations contained within the Berkson *et al.* (May 2011) ORCS Working Group NOAA Technical Memorandum and previous technical guidance from NMFS (*i.e.,* Restrepo *et al.* (July 1998) NOAA Technical Memorandum) that indicate maximum landings should only be used in the catch statistic for lightly exploited non-target species.

Response: NMFS disagrees, and both the Council's SSC and the NMFS Southeast Fisheries Science Center (SEFSC) determined that the actions in Amendment 29 are based on the best scientific information available. The SSC and the Council considered the recommendations in the technical guidance from the Berkson *et al.* (May 2011) ORCS Working Group NOAA Technical Memo, which can be found in Appendix H of Amendment 29, and Restrepo *et al.* (1998), which can be found at *http://www.nmfs.noaa.gov/sfa/NSGtkgd.pdf,* and determined that the use of maximum landings for the catch statistic for the species addressed by Amendment 29 was appropriate based on the following considerations. The Chair of the SSC indicated that the stocks addressed through the ORCS approach in Amendment 29 are, for the most part, minor stocks, and the probability that they are already overexploited is lower than for the species that have been assessed. That is because for many of these unassessed species, catch is not directed but is incidental to other targeted species, and landings are episodic and highly variable, with some years of fairly high catches and other years of low catches. The SSC considered the use of a median, instead of maximum, catch statistic for these stocks, but was concerned that it would not adequately represent the high fluctuation in landings. Therefore, the SSC set the catch statistic at the upper bound of the band of landings during the time period 1999–2007 to account for the variability in catch, intending that the resulting ABC from using maximum landings as the catch statistic in ORCS would serve as a limit, not a target, and landings would be expected, on average, to be below the ABC. Accountability measures would be triggered if an ACL that resulted from the ABC was reached or projected to be reached. However, if the ABC is repeatedly exceeded, that would suggest that effort for a stock is not incidental but is directed and expanding, and Council action would be needed.

Comment 2: NMFS failed to take a hard look at the environmental consequences of its proposed action to set ABCs for species in Amendment 29. Peer-reviewed literature and scientific evidence presented to NMFS, the Council, and the SSC demonstrates that the use of catch scalars, that set an ABC level as a multiple of the maximum catch statistic or at the third highest historic landings, have high probabilities of overfishing and reduce long-term yields. Despite having been notified of these environmental consequences before and during scoping for Amendment 29, neither Amendment 29 nor the proposed rule addresses any of this scientific information or seeks to justify the rationale behind the decision based on the information presented to NMFS and the Council. Furthermore, NMFS has not taken a hard look at the significant new information that has come to light in recent publications.

Response: NMFS and the Council have taken a hard look at the environmental consequences of setting the ABCs for species in Amendment 29, including reviewing the recommendations from the ORCS Workgroup, the simulation approach presented to the SSC and the Council, and other information available during the development of the amendment. Studies by Newman *et al.* 2015 and a December 2014 report from the Natural Resources Defense Council, as cited by the commenter, were published after Amendment 29 was approved by the Council for submission to the Secretary of Commerce, and were not available during the development of the document. Because these additional studies did not indicate that drastic changes have occurred in the fishery, it was unnecessary to revise the management measures in Amendment 29 (50 CFR 600.315(e)(1)).

Additionally, during two workshops in August 2012 and April 2013, the Council's SSC discussed the ORCS approach for determining the ABCs of unassessed species in the South Atlantic, and extensively discussed the designation of a catch statistic used in the ORCS approach to specify the ABC for the 14 species in Amendment 29.

At the October 2013 SSC meeting, a member of the public who is an academic scientist, presented a simulation approach to inform the SSC about new methods they could consider. The simulation approach, which was subsequently published in March 2014, was conducted on two *assessed* species, porgy and snapper, and was not conducted on any of the 14 unassessed snapper-grouper species addressed by Amendment 29. The SSC discussed this simulation approach, but did not consider the presentation to be a relevant evaluation of how the ORCS method was applied to the *unassessed* stocks in Amendment 29. Instead, the SSC reiterated its prior endorsement, from its August 2012 workshop, of using the ORCS approach to revise the ABCs for 14 unassessed species with the maximum landings as the catch statistic. The SSC considered ORCS to be the best approach to allow the stocks to yield their historic average landings in the future.

At its March 2014 meeting, the Council was informed of a public comment expressing concerns with using maximum landings as the catch statistic for ORCS and received a presentation on the SSC's use of the ORCS method, and on the simulation approach, which was presented to the SSC in October 2013. At its June 2014 meeting, the Council further discussed the SSC's rationale for choosing maximum landings as a catch statistic in the ORCS approach, and discussed the report from the April 29–May 1, 2014, SSC Meeting which contains a dissenting opinion from one SSC member (addressed in the response to comment 3, below) regarding concerns with how the ORCS approach was being applied. Based on all the foregoing and for the reasons explained in the above response to comment 1, the Council decided to move forward with the proposed revisions to the ABC control rule as recommended by the SSC, with the understanding that further revisions to the ABC control rule may be warranted in the future.

Comment 3: One member of the SSC concluded that the ORCS approach was not based on the best available science and the associated catch level recommendations should not be used for fisheries management.

Response: During the discussion of Amendment 29 at the April 29–May 1, 2014, SSC Meeting, a few members of the SSC expressed concerns with the application of the ORCS approach and one member disagreed with the use of the ORCS approach and requested his position be presented as a ''minority opinion'' in the report of the April 29–May 1, 2014, SSC Meeting. The SSC member did not agree with the choice of catch statistics and associated scalars because he thought it would provide

less of a buffer for uncertainty than that prescribed for assessed species in the ABC control rule. However, despite this SSC member's individual opinion, the SSC reaffirmed its decision at that meeting and in the report of their April 29–May 1, 2014, meeting regarding the application of the ORCS approach to specify the catch level recommendations contained in Amendment 29. Further, the SSC confirmed that the ORCS approach, as applied in Amendment 29, still represents the best scientific information available and considered the associated catch level recommendations appropriate for management. NMFS finds that Amendment 29 is based on the best scientific information available.

Comment 4: A recent peer-reviewed article documents how the South Atlantic and Gulf of Mexico fishery management regions routinely and almost uniformly set ABCs for previously unassessed stocks above the long-term mean landings (*e.g.,* 3rd highest landings over 10 years or 2 standard deviations above the mean), while all other regions with large numbers of data-poor stocks take a more precautionary approach. The use of catch scalars that are set above historic mean landings/catch levels conflicts with the way catch scalars are applied throughout the rest of the country.

Response: NMFS disagrees. Information presented in the comment shows that the ABCs for a substantial portion of the data poor species from the Western Pacific Fishery Management Council are also set at levels greater than median and mean levels, and the Pacific Fishery Management Council also set ABCs at levels greater than median and mean levels for some species. The ABCs for species in the South Atlantic and Gulf of Mexico were based on recommendations from the Council's SSC and Gulf of Mexico Fishery Management Council's SSC, and were considered to be the best scientific information available at the time. In August 2012 and April 2013, the Council's SSC extensively discussed the designation of a catch statistic to be used in the ORCS approach for the unassessed species addressed in Amendment 29. For many of these unassessed species, catch is incidental to other targeted species, and landings are episodic and highly variable. The SSC considered the use of median landings as a catch statistic but was concerned that it would not adequately represent the high fluctuation in landings. By using maximum landings for the catch statistic in the ORCS approach, the SSC recommended an ABC that is a limit, not a target. The ABC is set slightly above the level where stock biomass and landings will vary naturally but average landings would be expected to be below the ABC. Accountability measures would be triggered if an ACL that resulted from the ABC was exceeded.

Comment 5: The Southeast Region's approach to stock assessment and ABC setting for data limited stocks leaves all of the analysis and decision making to the Councils and SSC with no substantive analytical support from expert stock assessment scientists in the SEFSC.

Response: The Magnuson-Stevens Fishery Conservation and Management Act National Standard 1 guidelines state that each fishery management council should establish an ABC control rule based on the scientific advice from its SSC (50 CFR 600.310(f)(4)). The ABCs are then recommended by the SSC to the fishery management council, usually through the application of the ABC control rule. The Council's SSC, which includes expert stock assessment scientists, including two scientists from the SEFSC during the development of Amendment 29, made recommendations for modifications to the ABC control rule and application of the ORCS approach contained in Amendment 29 during the SSC's extensive workshop discussions in August 2012 and April 2013.

The ABC control rule considers different levels and methods for setting ABCs, depending on the availability of data. For unassessed species, the control rule allows for the ABC to be determined using Depletion-Based Stock Reduction Analysis (DBSRA), Depletion-Corrected Average Catch (DCAC), third highest landings, or median landings. Amendment 29 modifies the ABC control rule to add the ORCS approach to the list of methods that can be used to calculate ABC values for unassessed stocks that may have only reliable catch data.

Regardless of which level of the ABC control rule is applied and which method is used, when the Council ultimately chooses an ABC in an amendment to the FMP, that amendment will be reviewed by the SEFSC to advise whether the amendment is based upon the best scientific information available. The SEFSC reviewed Amendment 29 and determined that it is based upon the best scientific information available. NMFS agrees with that determination.

Comment 6: Amendment 29 and the ABC control rule for the snapper-grouper fishery fail to incorporate and account for discard mortality in the ACL setting mechanism. The FMP, as amended by Amendment 29, fails to include a standardized bycatch reporting methodology (SBRM).

Response: NMFS disagrees. The ABC control rule for the snapper-grouper fishery was established in 2012 through the Comprehensive ACL Amendment, which amended the FMP. Applying the control rule requires consideration of different levels and methods for setting an ABC and considers discard mortality. As discussed above, Amendment 29 modifies the ABC control rule to add the ORCS approach to the list of methods that can be used to calculate ABC values for unassessed stocks. When employing the ORCS approach to specify the ABCs for the 14 species addressed in Amendment 29, the SSC considered discard mortality to calculate the risk of overexploitation. Their evaluation of discard mortality for a species included both the discard mortality rate and magnitude of discards. Thus, discard mortality was accounted for in setting the ACLs for the species in Amendment 29.

The FMP does contain an SBRM, and the SBRM uses a variety of sources to assess and monitor bycatch, such as those set forth in Amendment 15B to the FMP. Additionally, Amendment 29 includes a bycatch practicability analysis (Appendix F), which describes bycatch and discard information being collected for the species addressed in this amendment, and provides an overview of the programs to collect bycatch information for snapper-grouper species in the southeast region.

Additionally, in 2014, a workgroup was established in the southeast region to determine the effectiveness of the current SBRMs in all FMPs in the southeast region. This is an ongoing effort, and the workgroup will be providing recommendations on how to improve the SBRMs as needed in 2015. NMFS anticipates that if adjustments to SBRMs based on the recommendations of the workgroup are needed, they will be made through amendments to FMPs.

Comment 7: Amendment 29 does not comply with the National Environmental Policy Act in that it fails to consider a reasonable range of alternatives for Action 1 to update the ABC control rule. There are only two alternatives for Action 1, including the no action alternative. At the very least, the EA should have fully examined the impacts of the alternative catch scalars and other data-limited methods discussed in the ORCS Technical Memorandum, Restrepo *et al.* (1998), and the practices of other NMFS fishery management regions. These include the use of a more precautionary catch

statistic, such as the mean or median historic catch level, as well as alternative data-limited methods, such as DBSRA and DCAC.

Response: NMFS disagrees. A reasonable range of alternatives was considered in Amendment 29. In addition, the SSC and the Council considered the recommendations in technical guidance from the Berkson *et al.* (May 2011) ORCS Working Group NOAA Technical Memo, which can be found in Appendix H of Amendment 29, and Restrepo *et al.* (1998), which can be found at *http://www.nmfs.noaa.gov/sfa/NSGtkgd.pdf.* The use of mean or median historic catch levels, and DBSRA and DCAC data-limited methods, which are also used in other regions, are already a part of the Council's current ABC control rule. As such, they were considered by the Council as a component of Alternative 1, the no action alternative.

Action 1 analyzes two alternatives: Alternative 1, the no-action, status quo alternative; and Alternative 2, which adds the ORCS approach recommended to the Council by its SSC to the list of methods that can be used to determine an ABC. Under the ABC Control rule developed in Amendment 29, Level 1 is used for stocks with assessment information, DBSRA is used in Level 2, DCAC is used in Level 3, ORCS is used in Level 4, and the third highest or median landings is Level 5 of the updated ABC control rule.

The National Standard 1 guidelines state that ''for stocks and stock complexes required to have an ABC, each Council must establish an ABC control rule based on scientific advice from its SSC.'' The SSC provided no other options or modifications to the ABC control rule for the Council to consider. Therefore, the Council and NMFS determined that it was reasonable to analyze the two alternatives for modifications to the ABC control rule, and that there was no other reasonable alternative.

Comment 8: NMFS should have conducted an environmental impact statement (EIS) for the actions in Amendment 29.

Response: An EIS was conducted for the Comprehensive ACL Amendment, because that amendment first established the ABC control rule, applied the control rule to specify ABCs and ACLs for all snapper-grouper species and species managed under other FMPs, and also specified sector allocations. Amendment 29 proposes to modify one aspect of the ABC control rule through the addition of the ORCS approach, and utilize the ORCS approach to revise ABCs for 14 snapper-grouper species. For the reasons set forth in its EA, NMFS determined that the actions in Amendment 29 would not lead to significant biological, economic, social, or administrative impacts and that an EIS was not required. This determination was made in the finding of no significant impact.

Comment 9: Scientific advances in data-limited assessment methods and tools provide a more scientifically defensible and transparent framework for conducting an assessment and setting ABCs for data limited stocks. The Data-Limited Fisheries Toolkit should have been used to specify ABCs for data-limited stocks.

Response: The Data-Limited Fisheries Toolkit was referenced in a 2015 publication by Newman *et al.* and in a December 2014 report from the Natural Resources Defense Council. Amendment 29 was approved by the Council in September 2014 and the toolkit was not available for consideration during the development of the amendment. Because this additional information did not indicate that drastic changes have occurred in the fishery, it was unnecessary to revise the management measures in Amendment 29 (50 CFR 600.315(e)(1)). However, the SEFSC is planning to examine the use of the toolkit at data limited workshops in the Caribbean and Gulf of Mexico, and there is potential for use of the toolkit in the South Atlantic in the future.

Comment 10: How are the estimates for recreational landings of gray triggerfish determined?

Response: Recreational landings for gray triggerfish and other snapper-grouper species are collected through the Marine Recreational Information Program (MRIP), and the Southeast Region Headboat Survey (SRHS). In the southeast region, MRIP covers both coastal Atlantic states from Maine to Florida and Gulf of Mexico coastal states from Florida to Louisiana. (Texas provides data on recreational landings through their coastal creel survey conducted by the Texas Division of Parks and Wildlife.) MRIP provides estimated landings and discards for six 2-month periods (waves) each year. The survey provides estimates for three recreational fishing modes: Shore based fishing, private and rental boat fishing, and for-hire charter and guide fishing. Catch data are collected through dockside angler intercept surveys of completed recreational fishing trips and effort data are collected using telephone surveys. The SRHS estimates landings and discards for headboats in the U.S. South Atlantic and Gulf of Mexico from required electronic logbooks. Landings data from MRIP and SRHS are compared to the recreational ACL. If the ACL has been met or exceeded, an accountability measure is triggered, such as an in-season closure. If landings for either MRIP or SRHS are incomplete, projections of landings based on information from previous years are used to predict when the ACL is expected to be met.

Comment 11: Closing gray triggerfish is going to be detrimental to the fishermen of South Carolina. There needs to be different regulations for different states. One management scheme does not fit all areas.

Response: To the extent practicable, an individual stock of fish shall be managed as a unit throughout its range, as required by National Standard 3 of the Magnuson-Stevens Act. However, NMFS agrees that one management scheme for gray triggerfish might not be appropriate for all areas of the South Atlantic, and Amendment 29 should allow more access to gray triggerfish by fishermen in North Carolina and South Carolina. Currently, commercial harvest for gray triggerfish opens on January 1, and closes when the commercial ACL is met. Fishermen in North Carolina and South Carolina sometimes have limited or no access to gray triggerfish in the early months of the year due to poor weather, and could risk unsafe conditions to fish at that time. Amendment 29 includes an action to change the current management scheme by dividing the annual commercial fishing season for gray triggerfish into two 6-month fishing seasons with two separate quotas to improve fishing opportunities for gray triggerfish throughout the South Atlantic and throughout the year. This action would allocate 50 percent of the commercial gray triggerfish ACL to the time period January 1 through June 30, and 50 percent to the time period July 1 through December 31. A split commercial season would likely increase access to gray triggerfish in North Carolina and South Carolina during times of the year when weather conditions are good. NMFS also expects that the split commercial season will align the commercial harvest of gray triggerfish with that of vermilion snapper, as these are two species are commonly caught together.

Comment 12: The minimum size limit for gray triggerfish should be 12 inches (30.5 cm), fork length (FL), for both recreational and commercial fishermen in state and Federal waters. The recreational bag limit should be five fish per person per day. Enforcement is hindered when rules are different for state and Federal waters.

Response: Currently there is no minimum size limit for gray triggerfish in Federal waters off North Carolina, South Carolina, and Georgia. This final rule specifies a minimum size limit for gray triggerfish of 12 inches (30.5 cm) FL in Federal waters off North Carolina, South Carolina, and Georgia. The current minimum size limit for gray triggerfish is 12 inches (30.5 cm), total length (TL), in Federal waters off the east coast of Florida. This final rule specifies a minimum size limit of 14 inches (35.6 cm) FL for gray triggerfish in Federal waters off the east coast of Florida. The Florida Fish and Wildlife Conservation Commission recently approved an increase in the minimum size limit for gray triggerfish from 12 inches (30.5 cm) FL to 14 inches (35.6 cm) FL in state waters off the east coast of Florida. The Council's purpose is to achieve consistency with Florida regulations and aid law enforcement, since a 14-inch (35.6 cm) FL minimum size limit for gray triggerfish is already in place for Federal and state waters off the west coast of Florida. Gray triggerfish are included in the Federal 20-fish aggregate snapper-grouper bag limit and Amendment 29 did not include an action to establish a more specific recreational bag limit for gray triggerfish. A stock assessment is currently underway for gray triggerfish, and the Council may consider adjustments to management measures for the species pending the outcome of the assessment.

Comment 13: The minimum size limit for gray triggerfish is unnecessary and will only add to discards the Council deducts from quotas every year with no benefit to the fish, fishermen, or consumer.

Response: This final rule includes management measures for gray triggerfish to modify the minimum size limit for the commercial and recreational sectors, implement a split commercial season and a commercial trip limit. The Council determined that these management measures were needed to provide biological benefits for gray triggerfish and lengthen the fishing season.

Because most gray triggerfish currently retained are larger than the 12-inch (30.5-cm) FL minimum size limit included in this final rule for commercial and recreational fishermen off Georgia and the Carolinas, increased discards are not expected. Regulatory discards would be expected to increase with a 14-inch (35.6-cm) FL fork length minimum size limit; however, the survival of released fish is estimated to be high (87.5 percent). The establishment of a 12-inch (30.5-cm) FL minimum size limit off Georgia and the Carolinas, as well as an increase in the minimum size limit off the east coast of Florida is expected to have increased biological benefits for gray triggerfish through improved spawning opportunities. Thus, increased biological benefits associated with spawning opportunities at larger size limits would offset negative effects of the low level of mortality associated with a small increase in regulatory discards. The combined effect of the commercial management measures proposed for gray triggerfish is expected to benefit fishermen by lengthening the commercial fishing season.

Comment 14: The commercial trip limit does nothing to avoid closures or regulatory discards. The gray triggerfish quota should be managed with a 100 lb (45 kg) bycatch allowance for the final 25 percent of each seasonal quota to limit closures and discards. This would follow the Magnuson-Stevens Act mandates to limit waste and make efficient use of our resources. Failure to follow these mandates should result in non-compliant amendments getting sent back to the Council with instructions to correct its mistakes.

Response: Closures would still be expected if the gray triggerfish quota was managed with a 100 lb (45 kg) bycatch allowance for the final 25 percent of each seasonal quota. The Council selected a 1,000-lb (454 kg), round weight, trip limit as its preferred alternative. The Council considered various commercial trip limit alternatives, including an alternative that would reduce the commercial trip limit to 200 lb (91 kg), round weight, for the final 25 percent of each seasonal quota. Analysis provided in Amendment 29 indicated that a step-down in the trip limit to 200 lb (91 kg), round weight, would lengthen the season by only a small amount, and would provide little economic benefit to fishermen. Regulatory discards of gray triggerfish can be expected after an ACL is reached or after a small trip limit is reached if fishermen are targeting co-occurring species. However, in situations where there are discarded gray triggerfish due to regulations, survival of released gray triggerfish is estimated to be high (87.5 percent).

Classification

The Regional Administrator, Southeast Region, NMFS has determined that this final rule is necessary for the conservation and management of South Atlantic snapper-grouper species and is consistent with Amendment 29, the FMP, the Magnuson-Stevens Act, and other applicable law. This final rule has been determined to be not significant for purposes of Executive Order 12866. Pursuant to section 604 of the Regulatory Flexibility Act, NMFS prepared a Final Regulatory Flexibility Analysis (FRFA) for this final rule. The FRFA uses updated information, when available, and analyzes the anticipated economic impacts of the final actions and any significant economic impacts on small entities. The FRFA is below.

The description of the action, why it is being considered and the legal basis for the rule are contained in the preamble of the proposed rule and in the preamble of this final rule. Section 604(a)(2) of the RFA requires NMFS to summarize significant issues raised by the public in response to the IRFA, a summary of the assessment of such issues, and a statement of any changes made as a result of the comments. No significant issues were raised by the public in response to the IRFA.

Up to 681 commercial fishing vessels operate in the snapper-grouper fishery of the South Atlantic and NMFS estimates that up to 592 businesses will be directly affected; however, as explained below, the number is likely closer to 287. According to the Small Business Administration (SBA) size standards, a business in the finfish fishing industry (NAICS 114111) is considered a small business if it is independently owned and operated, is not dominant in its field of operation (including affiliates), and has combined annual receipts not in excess of $20.5 million. NMFS estimates that all of the directly affected businesses have annual revenues less than the size standard. Consequently, up to 592, but more likely closer to 287, small commercial fishing businesses own and operate the directly affected vessels. From 2009 through 2013, an annual average of 281 commercial fishing vessels landed gray triggerfish and 6 landed bar jack.

Anglers who catch snapper-grouper species in the South Atlantic exclusive economic zone will be directly affected; however, anglers are not considered small entities as that term is defined in 5 U.S.C. 601(6), whether fishing from for-hire fishing, private or leased vessels. Recreational for-hire fishing vessels will be indirectly affected.

Amendment 29 changes the ABC rule and assigns scalar values and risk tolerance levels for ORCS. These are administrative actions that do not have a direct economic impact on any small entity.

The rule revises the total and commercial ACLs for Atlantic spadefish, bar jack, gray triggerfish, scamp, grunts complex, shallow-water grouper

complex, and snappers complex. The commercial ACLs for scamp and the grunts complex will decrease, while the commercial ACLs for the other species and species complexes will increase. Because baseline commercial landings are less than the current and revised commercial ACLs for Atlantic spadefish, scamp, grunts complex, shallow-water grouper complex, and snappers complex, NMFS expects no impact on annual landings of and associated dockside revenues from these five species and species complexes.

NMFS expects the revised commercial ACL for gray triggerfish to increase annual dockside revenue from gray triggerfish landings from $44,118 to $66,674 (2013 dollars). Florida businesses would receive approximately 14 percent to 27 percent of those benefits ($6,177 to $18,002) and North Carolina, South Carolina, and Georgia businesses would receive from 86 percent to 73 percent ($57,340 to $32,206). Divided across all 592 businesses, the average annual increase in dockside revenue from gray triggerfish landings would range from approximately $75 to $113 (2103 dollars) per business. However, the number of small businesses directly affected is likely less than that. From 2009 through 2013, an annual average of 281 vessels landed gray triggerfish. The average annual benefit would range from approximately $157 to $237 (2013 dollars) per small business across 281 small businesses.

NMFS expects the revised commercial ACL for bar jack to increase average annual dockside revenue from bar jack landings from $0 to $1,943 (2013 dollars), and divided across all 592 businesses, the average annual benefit would range from $0 to approximately $3 (2013 dollars) per business. However, if that benefit is divided across the average of six vessels with bar jack landings annually from 2009 through 2013, the average annual benefit would range from $0 to $324 (2013 dollars) per small business.

This rule revises the minimum size limit for gray triggerfish to 12 inches (30.5 cm) FL in Federal waters off North Carolina, South Carolina, and Georgia, and 14 inches (35.6 cm) FL off the east coast of Florida. NMFS estimates that these minimum size limits will reduce baseline commercial landings of gray triggerfish in North Carolina, South Carolina, and Georgia from 1 percent to 3 percent and in Florida from 14 percent to 22 percent. These size limits are expected to reduce average annual dockside revenue from gray triggerfish landings from $14,775 to $42,595 in the region as a whole. NMFS estimates these impacts will not be shared equally across the region. NMFS estimates that average annual dockside revenue from gray triggerfish landings could decrease. That average decrease can range from $10,269 to $31,121 (2013 dollars) in Florida and from $3,825 to $13,517 (2013 dollars) in the other three states. The average loss of dockside revenue per small business could range from $53 to $151 in Florida (with 205 businesses) and from $50 to $178 in the other three states (with 76 businesses).

NMFS estimates the combined changes of the commercial ACL and minimum size limits for gray triggerfish to yield a net increase in average annual dockside revenue from gray triggerfish landings in the combined states of North Carolina, South Carolina, and Georgia. The average annual net benefit could range from $18,689 to $53,515 (2013 dollars). With an estimated 76 businesses annually landing gray triggerfish in these states, the average annual increase could range from $246 to $704 per small business. The combined changes of the commercial ACL and minimum size limit for gray triggerfish are estimated to produce a net decrease in dockside revenue from gray triggerfish landings in Florida in four of six baseline scenarios. The net average annual loss could range from $1,803 to $24,945 in the state. In two scenarios, however, Florida businesses could collectively receive an average net gain in dockside revenue from $398 to $7,733. With an estimated 205 small businesses in Florida that annually land gray triggerfish, the average annual net loss of dockside revenue from gray triggerfish landings could be from $9 to $122 or the average annual net gain could be from $2 to $38 per small business.

This rule will divide the commercial season for gray triggerfish into two 6-month seasons, with each season receiving 50 percent of the commercial ACL. NMFS expects the split seasons to have no effect on annual landings or dockside revenues. However, the divided commercial season will provide small businesses an increased opportunity to fish for gray triggerfish in the summer months when weather conditions are more favorable.

This rule will establish a commercial trip limit for gray triggerfish of 1,000 lb (454 kg), round weight, which is expected to increase the number of days that each season is open; however, NMFS also expects no change in annual landings and dockside revenues. From 2009 through 2013, an annual average of 10 percent of vessels with landings of gray triggerfish had landings that exceeded the trip limit. This indicates 28 vessels and small businesses that annually land the species could be directly affected. These 28 vessels will either have less annual landings and dockside revenue from the same number of trips or have to increase the number of trips to maintain landings and dockside revenues at their current levels. These 28 vessels may be larger than the average vessel and the trip limit could decrease their net revenue per pound by increasing their average cost per pound. There is insufficient information, however, to estimate the impact, if any, on net revenues from gray triggerfish landings.

The net annual benefit is the sum of an average annual increase in dockside revenues ranging from $44,118 to $68,617 and an average annual decrease in dockside revenues ranging from $14,778 to $42,595. This results in a collective net annual benefit ranging from $1,523 to $53,839 to 287 small businesses.

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as small entity compliance guides. As part of the rulemaking process, NMFS prepared a fishery bulletin, which also serves as a small entity compliance guide. The fishery bulletin will be sent to all interested parties.

List of Subjects in 50 CFR Part 622

Annual catch limit, Annual catch target, Commercial trip limit, Fisheries, Fishing, Quotas, Size limit, Snapper-grouper, South Atlantic.

Dated: May 26, 2015.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, 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 OF MEXICO, 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 § 622.185, paragraph (c)(2) is revised to read as follows:

§ 622.185 Size limits.

* * * * *

(c) * * *

(2) *Gray triggerfish.* (i) *In the South Atlantic EEZ off Florida*—14 inches (35.6 cm), FL.

(ii) *In the South Atlantic EEZ off North Carolina, South Carolina, and Georgia*—12 inches (30.5 cm), FL.

* * * * *

■ 3. In § 622.190, add paragraph (a)(8) and revise the heading of paragraph (c)(1) to read as follows:

§ 622.190 Quotas.

* * * * *

(a) * * *

(8) *Gray triggerfish.* (i) For the period January through June each year—156,162 lb (70,834 kg), round weight.

(ii) For the period July through December each year—156,162 lb (70,834 kg), round weight.

(iii) Any unused portion of the quota specified in paragraph (a)(8)(i) of this section will be added to the quota specified in paragraph (a)(8)(ii) of this section. Any unused portion of the quota specified in paragraph (a)(8)(ii) of this section, including any addition of quota specified in paragraph (a)(8)(i) of this section that was unused, will become void and will not be added to any subsequent quota.

* * * * *

(c) * * *

(1) *South Atlantic gag, greater amberjack, snowy grouper, golden tilefish, vermilion snapper, black sea bass, red porgy, wreckfish, and gray triggerfish.* * * *

* * * * *

■ 4. In § 622.191, paragraph (a)(11) is added to read as follows:

§ 622.191 Commercial trip limits.

* * * * *

(a) * * *

(11) *Gray triggerfish.* Until the applicable quota specified in either § 622.190(a)(8)(i) or (ii) is reached, 1,000 lb (454 kg), round weight. See § 622.190(c)(1) for the limitations regarding gray triggerfish after either quota specified in § 622.190(a)(8)(i) or (ii) is reached or projected to be reached.

* * * * *

■ 5. In § 622.193:

■ a. The first sentence of paragraphs (i)(1)(i), (i)(2), (j)(1)(i), (j)(2), (m)(1)(i), (m)(2), (p)(1)(i), (p)(2), (q)(1)(i), (q)(2), (t)(1)(i), and (t)(2) are revised;

■ b. Paragraph (x) is revised; and

■ c. The heading for paragraph (p) is revised.

The revisions read as follows:

§ 622.193 Annual catch limits (ACLs), annual catch targets (ACTs), and accountability measures (AMs).

* * * * *

(i) * * *

(1) * * *

(i) If commercial landings for scamp, as estimated by the SRD, reach or are projected to reach the commercial ACL of 219,375 lb (99,507 kg), round weight, 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. * * *

* * * * *

(2) *Recreational sector.* If recreational landings for scamp, as estimated by the SRD, exceed the recreational ACL of 116,369 lb (52,784 kg), round weight, then during the following fishing year, recreational landings will be monitored for a persistence in increased landings and, if necessary, the AA will file a notification with the Office of the Federal Register, to reduce the length of the following recreational fishing season by the amount necessary to ensure recreational landings do not exceed the recreational ACL in the following fishing year. * * *

(j) * * *

(1) * * *

(i) If commercial landings for other SASWG, as estimated by the SRD, reach or are projected to reach the commercial ACL of 55,542 lb (25,193 kg), round weight, the AA will file a notification with the Office of the Federal Register to close the commercial sector for this complex for the remainder of the fishing year. * * *

* * * * *

(2) *Recreational sector.* If recreational landings for other SASWG, as estimated by the SRD, exceed the recreational ACL of 48,648 lb (22,066 kg), round weight, then during the following fishing year, recreational landings will be monitored for a persistence in increased landings and, if necessary, the AA will file a notification with the Office of the Federal Register, to reduce the length of the following recreational fishing season by the amount necessary to ensure recreational landings do not exceed the recreational ACL in the following fishing year. * * *

* * * * *

(m) * * *

(1) * * *

(i) If commercial landings for bar jack, as estimated by the SRD, reach or are projected to reach the commercial ACL of 13,228 lb (6,000 kg), round weight, 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. * * *

* * * * *

(2) *Recreational sector.* If recreational landings for bar jack, as estimated by the SRD, exceed the recreational ACL of 49,021 lb (22,236 kg), round weight, then during the following fishing year, recreational landings will be monitored for a persistence in increased landings and, if necessary, the AA will file a notification with the Office of the Federal Register, to reduce the length of the following recreational fishing season by the amount necessary to ensure recreational landings do not exceed the recreational ACL in the following fishing year. * * *

* * * * *

(p) *Other snappers complex (including cubera snapper, gray snapper, lane snapper, dog snapper, and mahogany snapper)*—(1) * * *(i) If commercial landings combined for this other snappers complex, as estimated by the SRD, reach or are projected to reach the complex commercial ACL of 344,884 lb (156,437 kg), round weight, the AA will file a notification with the Office of the Federal Register to close the commercial sector for this complex for the remainder of the fishing year. * * *

* * * * *

(2) *Recreational sector.* If the combined recreational landings for this other snappers complex, as estimated by the SRD, exceed the recreational ACL of 1,172,832 lb (531,988 kg), round weight, then during the following fishing year, recreational landings will be monitored for a persistence in increased landings and, if necessary, the AA will file a notification with the Office of the Federal Register, to reduce the length of the following recreational fishing season by the amount necessary to ensure recreational landings do not exceed the recreational ACL for this complex in the following fishing year. * * *

(q) * * *

(1)* * *

(i) If commercial landings for gray triggerfish, as estimated by the SRD, reach or are projected to reach the applicable commercial ACL (commercial quota) specified in § 622.190(a)(8)(i) or (ii), the AA will file a notification with the Office of the Federal Register to close the commercial sector for that portion of the fishing year applicable to the respective quota. * * *

* * * * *

(2) *Recreational sector.* If recreational landings for gray triggerfish, as estimated by the SRD, exceed the recreational ACL of 404,675 lb (183,557 kg), round weight, then during the following fishing year, recreational landings will be monitored for a persistence in increased landings and, if necessary, the AA will file a notification with the Office of the Federal Register,

to reduce the length of the following recreational fishing season by the amount necessary to ensure recreational landings do not exceed the recreational ACL in the following fishing year. * * *

* * * * *

(t) * * *

(1) * * *

(i) If commercial landings for Atlantic spadefish, as estimated by the SRD, reach or are projected to reach the commercial ACL of 150,552 lb (68,289 kg), round weight, 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. * * *

* * * * *

(2) *Recreational sector.* If recreational landings for Atlantic spadefish, as estimated by the SRD, exceed the recreational ACL of 661,926 lb (300,245 kg), round weight, then during the following fishing year, recreational landings will be monitored for a persistence in increased landings and, if necessary, the AA will file a notification with the Office of the Federal Register, to reduce the length of the following recreational fishing season by the amount necessary to ensure recreational landings do not exceed the recreational ACL in the following fishing year. * * *

* * * * *

(x) *Grunts complex (including white grunt, sailor's choice, tomtate, and margate)*—(1) *Commercial sector.* (i) If commercial landings for the grunts complex, as estimated by the SRD, reach or are projected to reach the commercial complex ACL of 217,903 lb (98,839 kg), round weight, the AA will file a notification with the Office of the Federal Register to close the commercial sector for this complex for the remainder of the fishing year. On and after the effective date of such a notification, all sale or purchase of the grunts complex is prohibited, and harvest or possession of these species in or from the South Atlantic EEZ is limited to the bag and possession limits. These bag and possession limits apply in the South Atlantic on board a vessel for which a valid Federal commercial or charter vessel/headboat permit for South Atlantic snapper-grouper has been issued, without regard to where such species were harvested, *i.e.,* in state or Federal waters.

(ii) If the combined commercial landings for the grunts complex exceed the ACL, and at least one of the species in the complex is 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.

(2) *Recreational sector.* If recreational landings for the grunts complex, as estimated by the SRD, exceed the recreational ACL of 618,122 lb (280,375 kg), round weight, then during the following fishing year, recreational landings will be monitored for a persistence in increased landings and, if necessary, the AA will file a notification with the Office of the Federal Register, to reduce the length of the following recreational fishing season for the grunts complex by the amount necessary to ensure recreational landings do not exceed the recreational ACL in the following fishing year. However, the length of the recreational season will not be reduced during the following fishing year if the RA determines, using the best scientific information available, that a reduction in the length of the following fishing season is unnecessary.

* * * * *

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Proposed Rules

Federal Register
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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.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 531

RIN 3206–AM88

General Schedule Locality Pay Areas

AGENCY: U.S. Office of Personnel Management.

ACTION: Proposed rule with request for comments.

SUMMARY: The U.S. Office of Personnel Management is issuing proposed regulations on behalf of the President's Pay Agent to link the definitions of General Schedule (GS) locality pay area boundaries to updated metropolitan area definitions established by the Office of Management and Budget in February 2013. Under this proposal, locations that would otherwise move to a lower-paying locality pay area due to use of the updated metropolitan area definitions in the locality pay program would remain in their current locality pay area. This proposal does not modify the current commuting and GS employment criteria used in the locality pay program to evaluate, for possible inclusion in a locality pay area, locations adjacent to the metropolitan area comprising the basic locality pay area. However, regarding calculation of commuting interchange rates used to evaluate such locations, the locality pay area definitions proposed in this document reflect use of the commuting patterns data collected as part of the American Community Survey between 2006 and 2010, as recommended by the Federal Salary Council in January 2014.

Under this proposal, 13 new locality pay areas would also be established. The Federal Salary Council recommended these 13 locality pay areas after reviewing pay levels in all ''Rest of U.S.'' metropolitan statistical areas and combined statistical areas with 2,500 or more GS employees. The Federal Salary Council found that the percentage difference between GS and non-Federal pay levels for the same levels of work—*i.e.,* the pay disparity—in these 13 locations was substantially greater than the ''Rest of U.S.'' pay disparity over an extended period. The President's Pay Agent has agreed to issue proposed regulations in response to the Federal Salary Council's recommendation to establish the 13 new locality pay areas. Locality pay rates for the new locality pay areas would be set by the President after the new locality pay areas would be established by regulation.

DATES: We must receive comments on or before July 1, 2015.

ADDRESSES: You may submit comments, identified by ''RIN 3206–AM88,'' by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Email: pay-leave-policy@opm.gov. Include ''RIN 3206–AM88'' in the subject line of the message.

Fax: (202) 606–0824.

Mail: Brenda L. Roberts, Deputy Associate Director for Pay and Leave, Office of Personnel Management, Room 7H31, 1900 E Street NW., Washington, DC 20415–8200.

FOR FURTHER INFORMATION CONTACT: Joe Ratcliffe, (202) 606–2838; fax: (202) 606–0824; email: *pay-leave-policy@opm.gov.*

SUPPLEMENTARY INFORMATION: Section 5304 of title 5, United States Code (U.S.C.), authorizes locality pay for General Schedule (GS) employees with duty stations in the United States and its territories and possessions. Section 5304(f) of title 5 U.S.C. authorizes the President's Pay Agent (the Secretary of Labor, the Director of the Office of Management and Budget (OMB), and the Director of the Office of Personnel Management (OPM)) to determine locality pay areas. The boundaries of locality pay areas must be based on appropriate factors, which may include local labor market patterns, commuting patterns, and the practices of other employers. The Pay Agent must give thorough consideration to the views and recommendations of the Federal Salary Council, a body composed of experts in the fields of labor relations and pay policy and representatives of Federal employee organizations. The President appoints the members of the Federal Salary Council, which submits annual recommendations to the Pay Agent on the locality pay program. The establishment or modification of locality pay area boundaries must conform with the notice and comment provisions of the Administrative Procedure Act (5 U.S.C. 553).

This proposal provides notice and invites comment on proposed regulations to implement the Pay Agent's plan to link locality pay area definitions to OMB-defined metropolitan areas, to use new commuting patterns data for evaluating locations adjacent to the metropolitan area comprising the basic locality pay area, and to establish 13 new locality pay areas. (Annual Pay Agent reports on locality pay can be found posted on the OPM Web site at *http://www.opm.gov/policy-data-oversight/pay-leave/pay-systems/general-schedule/#url=Pay-Agent-Reports.* The Pay Agent announced its plan to propose regulations linking locality pay area boundaries to OMB-defined metropolitan areas and using new commuting patterns data in its June 2014 report on locality pay. The Pay Agent announced its plan to establish 12 of the 13 new locality pay areas in its May 2013 report on locality pay. The Federal Salary Council, in its November 2014 recommendations, recommended establishing Kansas City, MO–KS, as a new locality pay area. Because the Federal Salary Council used the same selection criteria as used for the 12 new locality pay areas the Pay Agent tentatively approved, the Pay Agent proposes establishing Kansas City, MO–KS as a new locality pay area.)

Linking Locality Pay Area Boundaries to OMB-Defined Metropolitan Areas

OMB-defined metropolitan areas have been the basis of locality pay area boundaries since locality pay was implemented in 1994. OMB periodically updates its definitions of metropolitan areas, and regulations defining locality pay areas normally allow any minor changes in OMB-defined metropolitan areas to be reflected in locality pay area definitions automatically. However, because we anticipated significant changes to metropolitan area definitions in 2013, in January 2013, we revised the regulations defining locality pay areas so that updates based on OMB's redefinitions would not automatically be reflected in locality pay area definitions. (See **Federal Register** Vol. 78, No. 16, page 5115, January 24, 2013,

and the current definitions of ''CSA'' and ''MSA'' in 5 CFR 531.602.) That action provided time for the Federal Salary Council and the Pay Agent to review the updated metropolitan area definitions for suitability for use in the locality pay program. As a result, locality pay area definitions were frozen and are currently based on December 2009 OMB-defined metropolitan areas.

In February 2013, OMB issued new metropolitan area definitions, and in its January 2014 recommendations to the Pay Agent, the Federal Salary Council recommended that the Pay Agent use the February 2013 metropolitan area definitions in the locality pay program. The Pay Agent, in its June 2014 report to the President on locality pay, tentatively approved that recommendation, pending the issuance of revised locality pay regulations. This proposed rule would implement the change by revising the definitions of ''CSA'' and ''MSA'' in 5 CFR 531.602, to link the definitions of locality pay areas to the February 2013 OMB-defined metropolitan areas, and by updating the locality pay area definitions in 5 CFR 531.603 accordingly. The proposed revisions to the definitions of ''CSA'' and ''MSA'' in 5 CFR 531.602 would provide that any OMB additions to the CSAs and MSAs comprising basic locality pay areas would be reflected in locality pay area definitions automatically. The proposed rule also implements the Pay Agent's plan to retain, in their current locality pay area, any locations that would otherwise move to a lower-paying locality pay area as a result of linking locality pay area definitions to the February 2013 OMB-defined metropolitan areas, as recommended by the Federal Salary Council. Under this proposed rule, any such retained area would no longer be part of the basic locality pay area due to use of the February 2013 OMB-defined metropolitan areas and would be treated as an area of application.

OMB-defined metropolitan areas are called Core-Based Statistical Areas (CBSAs) and are grouped into three categories: Micropolitan Statistical Areas, where the largest included urban area has a population of 10,000 to 49,999; Metropolitan Statistical Areas (MSAs), where the largest included urban area has a population of 50,000 or more; and Combined Statistical Areas (CSAs), which are composed of two or more adjacent CBSAs with an employment interchange measure of at least 15 percent. (The employment interchange measure is the sum of the percentage of workers living in the smaller entity who work in the larger entity and the percentage of employment in the smaller entity that is accounted for by workers who reside in the larger entity.) CBSA definitions used for the locality pay program under this proposal are contained in OMB Bulletin 13–01 of February 28, 2013, and are available at *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf.*

Criteria for Areas of Application

As explained in the June 2014 Pay Agent report, locality pay areas consist of 1) the main metropolitan area comprising the basic locality pay area and, where criteria recommended by the Federal Salary Council and approved by the Pay Agent are met, 2) areas of application. Areas of application are locations that are adjacent to the basic locality pay area and meet approved criteria for inclusion in the locality pay area.

Current criteria for evaluating locations adjacent to a basic locality pay area for possible inclusion in the locality pay area as areas of application are as follows: For adjacent CSAs and adjacent multi-county MSAs the criteria are 1,500 or more GS employees and a commuting interchange rate of at least 7.5 percent. For adjacent single counties, the criteria are 400 or more GS employees and a commuting interchange rate of at least 7.5 percent. The commuting interchange rate is defined as the sum of the percentage of employed residents of the area under consideration who work in the basic locality pay area and the percentage of the employment in the area under consideration that is accounted for by workers who reside in the basic locality pay area.

The locality pay program also has criteria for evaluating Federal facilities that cross county lines into a separate locality pay area. To be included in an adjacent locality pay area, the whole facility must have at least 500 GS employees, with the majority of those employees in the higher-paying locality pay area, or that portion of a Federal facility outside of a higher-paying locality pay area must have at least 750 GS employees, the duty stations of the majority of those employees must be within 10 miles of the separate locality pay area, and a significant number of those employees must commute to work from the higher-paying locality pay area.

New Commuting Patterns Data

As stated in the June 2014 Pay Agent report, new commuting patterns data were collected as part of the American Community Survey from 2006 to 2010, and the Federal Salary Council recommended, in its January 2014 recommendations, using those data for evaluating potential areas of application. The Pay Agent tentatively agreed in its June 2014 report that it would be appropriate to use the new commuting patterns data for evaluating potential areas of application, and the areas of application included in the locality pay area definitions in this proposed rule, at 5 CFR 531.603(b), reflect use of the new commuting patterns data for that purpose.

Locations Almost or Completely Surrounded by Higher-Paying Locality Pay Areas

In its November 2012 recommendations, the Federal Salary Council noted that, if its recommendations for changing pay area boundaries were adopted, some areas currently in the ''Rest of U.S.'' locality pay area and not meeting the criteria for areas of application would be almost or completely surrounded by higher-paying locality pay areas. The Federal Salary Council recommended that completely surrounded locations be added to the locality pay area with which the surrounded location has the highest level of commuting to and from the basic locality pay area. For locations almost but not completely surrounded by higher-paying locality pay areas, the Federal Salary Council recommended that the Pay Agent evaluate, on a case-by-case basis, any locations almost but not completely surrounded by separate pay areas. The Federal Salary Council reiterated those recommendations in its January 2014 recommendations.

Without criteria to address locations completely surrounded by higher-paying locality pay areas, this proposal's changes to locality pay area boundaries would leave Kent County, MD, and Lancaster County, PA, in the ''Rest of U.S.'' locality pay area, and both counties could also be completely surrounded by higher-paying locality pay areas. The Pay Agent believes that single-county locations completely surrounded by higher-paying locality pay areas should be included in the locality pay area with the highest commuting interchange rate between the surrounded county and the basic locality pay area. Accordingly, this proposed rule would amend the locality pay area definitions at 5 CFR 531.603(b) to include Kent County, MD, in the Washington-Baltimore-Arlington, DC–MD–VA–WV–PA locality pay area and Lancaster County, PA, in the Harrisburg-York-Lebanon, PA, locality pay area.

The issue of how to address ''Rest of U.S.'' locations that are almost but not completely surrounded by higher-paying locality pay areas requires

careful consideration. The Pay Agent's preliminary view is that partially surrounded locations warranting some action would most likely be single ''Rest of U.S.'' counties—not multi-county metropolitan areas or large groups of counties—that are bordered by multiple higher-paying locality pay areas or are surrounded by water and isolated as ''Rest of U.S.'' locations within a reasonable commuting distance of a higher-paying locality pay area. The Pay Agent believes any such ''Rest of U.S.'' locations considered for inclusion in a separate locality pay area should be evaluated with criteria designed to evaluate such locations. The Pay Agent invites public comment on this issue.

Effect of Changes to Locality Pay Area Boundaries

This proposal would amend 5 CFR 531.603(b) to add the following locations to existing locality pay areas:

Atlanta—Athens-Clarke County—Sandy Springs, GA

Clarke County, GA; Gordon County, GA; Jackson County, GA; Madison County, GA; Morgan County, GA; Oconee County, GA; and Oglethorpe County, GA.

Boston-Worcester-Providence, MA-RI-NH-CT-ME

Androscoggin County, ME; Cumberland County, ME; Sagadahoc County, ME; and all portions of York County, ME, that are currently in the ''Rest of U.S.'' locality pay area.

Chicago-Naperville, IL-IN-WI

Bureau County, IL; LaSalle County, IL; and Putnam County, IL.

Cincinnati-Wilmington-Maysville, OH-KY-IN

Mason County, KY, and Union County, IN.

Cleveland-Akron-Canton, OH

Carroll County, OH; Erie County, OH; Huron County, OH; Stark County, OH; and Tuscarawas County, OH.

Columbus-Marion-Zanesville, OH

Guernsey County, OH; Hocking County, OH; Logan County, OH; Muskingum County, OH; and Perry County, OH.

Dallas-Fort Worth, TX–OK

Bryan County, OK; Hopkins County, TX; and Navarro County, TX.

Dayton-Springfield-Sidney, OH

Shelby County, OH.

Houston-The Woodlands, TX

Trinity County, TX; Washington County, TX; and Wharton County, TX.

Huntsville-Decatur-Albertville, AL

Marshall County, AL.

Indianapolis-Carmel-Muncie, IN

Decatur County, IN; Delaware County, IN; and Jackson County, IN.

Los Angeles-Long Beach, CA

All portions of Kern County, CA, currently included in the ''Rest of U.S.'' locality pay area.

Miami-Fort Lauderdale-Port St. Lucie, FL

Indian River County, FL; Martin County, FL; Okeechobee County, FL; and St. Lucie County, FL.

Milwaukee-Racine-Waukesha, WI

Dodge County, WI; Jefferson County, WI; and Walworth County, WI.

Minneapolis-St. Paul, MN-WI

Le Sueur County, MN; Mille Lacs County, MN; and Sibley County, MN.

New York-Newark, NY-NJ-CT-PA

Carbon County, PA; Lehigh County, PA; and Northampton County, PA.

Pittsburgh-New Castle-Weirton, PA-OH-WV

Jefferson County, OH; Indiana County, PA; Brooke County, WV; and Hancock County, WV.

Portland-Vancouver-Salem, OR-WA

Benton County, OR; Linn County, OR; and Cowlitz County, WA.

Raleigh-Durham-Chapel Hill, NC

Lee County, NC; Robeson County, NC; Scotland County, NC; Vance County, NC; and all portions of Granville County, NC, currently included in the ''Rest of U.S.'' locality pay area.

Seattle-Tacoma, WA

Lewis County, WA.

Washington-Baltimore-Arlington, DC-MD-VA-WV-PA

Dorchester County, MD; Kent County, MD; Talbot County, MD; Franklin County, PA; and Rappahannock County, VA.

Establishing 13 New Locality Pay Areas

Locality pay is set by comparing GS and non-Federal pay rates for the same levels of work in each locality pay area. Non-Federal salary survey data used to set locality pay rates are collected by the Bureau of Labor Statistics (BLS). Over the last several years, BLS has developed a method that permits Occupational Employment Statistics (OES) data to be used for locality pay. OES data are available for all MSAs and CSAs in the country and permit evaluation of salary levels in many more locations than could be covered under the prior National Compensation Survey alone.

The Federal Salary Council reviewed pay comparisons of GS and non-Federal pay in all ''Rest of U.S.'' MSAs and CSAs with 2,500 or more GS employees as of June 2011. Based on its review, the Federal Salary Council recommended new locality pay areas be established for 12 metropolitan areas with pay gaps averaging more than 10 percentage points above that for the ''Rest of U.S.'' locality pay area over an extended period. The Federal Salary Council's recommendations are posted on the OPM Web site at *http://www.opm.gov/policy-data-oversight/pay-leave/pay-systems/general-schedule/federal-salary-council/recommendation12.pdf.* In its November 2014 recommendations, using the same selection methodology, the Federal Salary Council recommended that Kansas City, MO–KS, also be established as a separate locality pay area.

The President's Pay Agent has agreed to issue proposed regulations in response to the Federal Salary Council's recommendation to establish 13 new locality pay areas and proposes to modify 5 CFR 531.603(b) to add the new locality pay areas. The 13 new locality pay areas proposed are Albany-Schenectady, NY; Albuquerque-Santa Fe-Las Vegas, NM; Austin-Round Rock, TX; Charlotte-Concord, NC–SC; Colorado Springs, CO; Davenport-Moline, IA–IL; Harrisburg-York-Lebanon, PA; Laredo, TX; Kansas City-Overland Park-Kansas City, MO–KS; Las Vegas-Henderson, NV–AZ; Palm Bay-Melbourne-Titusville, FL; St. Louis-St. Charles-Farmington, MO–IL; and Tucson-Nogales, AZ. Locality pay rates for the 13 new locality pay areas would be set by the President at a later date after they would be established by regulation.

Adjacent Areas Qualifying as Areas of Application to New Locality Pay Areas

Applying the criteria explained above for evaluating locations adjacent to basic locality pay areas as areas of application, this proposed rule would add the following counties to the new locality pay areas at 5 CFR 531.603(b): Fremont County, CO, and Pueblo County, CO, to the Colorado Springs, CO, locality pay area; Lancaster County, PA, to the Harrisburg-York-Lebanon, PA, locality pay area; Jackson County, KS, Jefferson County, KS, Osage County,

KS, Shawnee County, KS, and Wabaunsee County, KS to the Kansas City-Overland Park-Kansas City, MO–KS, locality pay area; and Cochise County, AZ, to the Tucson-Nogales, AZ, locality pay area.

Regarding the criteria explained above for evaluating Federal facilities that cross locality pay area boundaries, the Pay Agent is not aware of any Federal facilities that qualify for inclusion in the new locality pay areas under these criteria.

Impact and Implementation

Using February 2013 CBSA definitions as the basis for locality pay area boundaries and using updated commuting patterns data to evaluate potential areas of application would add a number of counties now covered by ''Rest of U.S.'' locality pay to higher-paying locality pay areas, which would impact about 6,300 GS employees.

The proposal to establish 13 new locality pay areas would impact about 102,000 GS employees. Implementing that proposal would not automatically change locality pay rates now applicable in those areas because locality pay percentages are established by Executive order under the President's authority in 5 U.S.C. 5304 or 5304a, and the President decides each year whether to increase locality pay percentages. When locality pay percentages are increased, past practice has been to allocate a percent of the total GS payroll for locality raises and to have the overall dollar cost for such pay raises be the same, regardless of the number of locality pay areas. If a percent of the total GS payroll is allocated for locality pay increases, the addition of new areas results in a smaller amount to allocate for locality pay increases in existing areas. Implementing higher locality pay rates in the 13 new locality pay areas could thus result in relatively lower pay increases for employees in existing locality pay areas than they would otherwise receive.

Executive Order 13563 and Executive Order 12866

OMB has reviewed this rule in accordance with E.O. 13563 and E.O. 12866.

Regulatory Flexibility Act

I certify that these regulations would not have a significant economic impact on a substantial number of small entities because they would apply only to Federal agencies and employees.

List of Subjects in 5 CFR Part 531

Government employees, Law enforcement officers, Wages.

Office of Personnel Management.

Katherine Archuleta,

Director.

Accordingly, OPM is proposing to amend 5 CFR part 531 as follows:

PART 531—PAY UNDER THE GENERAL SCHEDULE

■ 1. The authority citation for part 531 continues to read as follows:

Authority: 5 U.S.C. 5115, 5307, and 5338; sec. 4 of Pub. L. 103–89, 107 Stat. 981; and E.O. 12748, 56 FR 4521, 3 CFR, 1991 Comp., p. 316; Subpart B also issued under 5 U.S.C. 5303(g), 5305, 5333, 5334(a) and (b), and 7701(b)(2); Subpart D also issued under 5 U.S.C. 5335 and 7701(b)(2); Subpart E also issued under 5 U.S.C. 5336; Subpart F also issued under 5 U.S.C. 5304, 5305, and 5941(a), E.O. 12883, 58 FR 63281, 3 CFR, 1993 Comp., p. 682 and E.O. 13106, 63 FR 68151, 3 CFR, 1998 Comp., p. 224.

Subpart F—Locality-Based Comparability Payments

■ 2. In § 531.602, the definitions of CSA and MSA are revised to read as follows:

§ 531.602 Definitions.

* * * * *

CSA means the geographic scope of a Combined Statistical Area, as defined by the Office of Management and Budget (OMB) in OMB Bulletin No. 13–01, plus any areas subsequently added to the CSA by OMB.

* * * * *

MSA means the geographic scope of a Metropolitan Statistical Area, as defined by the Office of Management and Budget (OMB) in OMB Bulletin No. 13–01, plus any areas subsequently added to the MSA by OMB.

* * * * *

■ 3. In § 531.603, paragraph (b) is revised to read as follows:

§ 531.603 Locality pay areas.

* * * * *

(b) The following are locality pay areas for the purposes of this subpart:

(1) Alaska—consisting of the State of Alaska;

(2) Albany-Schenectady, NY—consisting of the Albany-Schenectady, NY CSA;

(3) Albuquerque-Santa Fe-Las Vegas, NM—consisting of the Albuquerque-Santa Fe-Las Vegas, NM CSA;

(4) Atlanta—Athens-Clarke County—Sandy Springs, GA–AL—consisting of the Atlanta—Athens-Clarke County—Sandy Springs, GA CSA and also including Chambers County, AL;

(5) Austin-Round Rock, TX—consisting of the Austin-Round Rock, TX MSA;

(6) Boston-Worcester-Providence, MA–RI–NH–CT–ME—consisting of the Boston-Worcester-Providence, MA–RI–NH–CT CSA, except for Windham County, CT, and also including Androscoggin County, ME, Cumberland County, ME, Sagadahoc County, ME, and York County, ME;

(7) Buffalo-Cheektowaga, NY—consisting of the Buffalo-Cheektowaga, NY CSA;

(8) Charlotte-Concord, NC-SC—consisting of the Charlotte-Concord, NC–SC CSA;

(9) Chicago-Naperville, IL-IN–WI—consisting of the Chicago-Naperville, IL–IN–WI CSA;

(10) Cincinnati-Wilmington-Maysville, OH-KY–IN—consisting of the Cincinnati-Wilmington-Maysville, OH–KY–IN CSA and also including Franklin County, IN;

(11) Cleveland-Akron-Canton, OH—consisting of the Cleveland-Akron-Canton, OH CSA;

(12) Colorado Springs, CO—consisting of the Colorado Springs, CO MSA and also including Fremont County, CO, and Pueblo County, CO;

(13) Columbus-Marion-Zanesville, OH—consisting of the Columbus-Marion-Zanesville, OH CSA;

(14) Dallas-Fort Worth, TX-OK—consisting of the Dallas-Fort Worth, TX–OK CSA and also including Delta County, TX, and Fannin County, TX;

(15) Davenport-Moline, IA-IL—consisting of the Davenport-Moline, IA–IL CSA;

(16) Dayton-Springfield-Sidney, OH—consisting of the Dayton-Springfield-Sidney, OH CSA and also including Preble County, OH;

(17) Denver-Aurora, CO—consisting of the Denver-Aurora, CO CSA and also including Larimer County, CO;

(18) Detroit-Warren-Ann Arbor, MI—consisting of the Detroit-Warren-Ann Arbor, MI CSA;

(19) Harrisburg-York-Lebanon, PA—consisting of the Harrisburg-York-Lebanon, PA CSA, except for and Adams County, PA, and York County, PA, and also including Lancaster County, PA;

(20) Hartford-West Hartford, CT–MA—consisting of the Hartford-West Hartford, CT CSA and also including Windham County, CT, Franklin County, MA, Hampden County, MA, and Hampshire County, MA;

(21) Hawaii—consisting of the State of Hawaii;

(22) Houston-The Woodlands, TX—consisting of the Houston-The Woodlands, TX CSA and also including San Jacinto County, TX;

(23) Huntsville-Decatur-Albertville, AL—consisting of the Huntsville-Decatur-Albertville, AL CSA;

(24) Indianapolis-Carmel-Muncie, IN—consisting of the Indianapolis-

Carmel-Muncie, IN CSA and also including Grant County, IN;

(25) Kansas City-Overland Park-Kansas City, MO–KS—consisting of the Kansas City-Overland Park-Kansas City, MO–KS CSA and also including Jackson County, KS, Jefferson County, KS, Osage County, KS, Shawnee County, KS, and Wabaunsee County, KS;

(26) Laredo, TX—consisting of the Laredo, TX MSA;

(27) Las Vegas-Henderson, NV–AZ—consisting of the Las Vegas-Henderson, NV–AZ CSA;

(28) Los Angeles-Long Beach, CA—consisting of the Los Angeles-Long Beach, CA CSA and also including Kern County, CA, and Santa Barbara County, CA;

(29) Miami-Fort Lauderdale-Port St. Lucie, FL—consisting of the Miami-Fort Lauderdale-Port St. Lucie, FL CSA and also including Monroe County, FL;

(30) Milwaukee-Racine-Waukesha, WI—consisting of the Milwaukee-Racine-Waukesha, WI CSA;

(31) Minneapolis-St. Paul, MN–WI—consisting of the Minneapolis-St. Paul, MN–WI CSA;

(32) New York-Newark, NY–NJ–CT–PA—consisting of the New York-Newark, NY–NJ–CT–PA CSA and also including all of Joint Base McGuire-Dix-Lakehurst;

(33) Palm Bay-Melbourne-Titusville, FL—consisting of the Palm Bay-Melbourne-Titusville, FL MSA;

(34) Philadelphia-Reading-Camden, PA–NJ–DE–MD—consisting of the Philadelphia-Reading-Camden, PA–NJ–DE–MD CSA, except for Joint Base McGuire-Dix-Lakehurst;

(35) Phoenix-Mesa-Scottsdale, AZ—consisting of the Phoenix-Mesa-Scottsdale, AZ MSA;

(36) Pittsburgh-New Castle-Weirton, PA–OH–WV—consisting of the Pittsburgh-New Castle-Weirton, PA–OH–WV CSA;

(37) Portland-Vancouver-Salem, OR–WA—consisting of the Portland-Vancouver-Salem, OR–WA CSA;

(38) Raleigh-Durham-Chapel Hill, NC—consisting of the Raleigh-Durham-Chapel Hill, NC CSA and also including Cumberland County, NC, Hoke County, NC, Robeson County, NC, Scotland County, NC, and Wayne County, NC;

(39) Richmond, VA—consisting of the Richmond, VA MSA and also including Cumberland County, VA, King and Queen County, VA, and Louisa County, VA;

(40) Sacramento-Roseville, CA–NV—consisting of the Sacramento-Roseville, CA CSA and also including Carson City, NV, and Douglas County, NV;

(41) San Diego-Carlsbad, CA—consisting of the San Diego-Carlsbad, CA MSA;

(42) San Jose-San Francisco-Oakland, CA—consisting of the San Jose-San Francisco-Oakland, CA CSA and also including Monterey County, CA;

(43) Seattle-Tacoma, WA—consisting of the Seattle-Tacoma, WA CSA and also including Whatcom County, WA;

(44) St. Louis-St. Charles-Farmington, MO–IL—consisting of the St. Louis-St. Charles-Farmington, MO–IL CSA;

(45) Tucson-Nogales, AZ—consisting of the Tucson-Nogales, AZ CSA and also including Cochise County, AZ;

(46) Washington-Baltimore-Arlington, DC–MD–VA–WV–PA—consisting of the Washington-Baltimore-Arlington, DC–MD–VA–WV–PA CSA and also including Kent County, MD, Adams County, PA, York County, PA, King George County, VA, and Morgan County, WV; and

(47) Rest of U.S.—consisting of those portions of the United States and its territories and possessions as listed in 5 CFR 591.205 not located within another locality pay area.

[FR Doc. 2015–13135 Filed 5–29–15; 8:45 am]

BILLING CODE 6325–39–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. APHIS–2014–0106]

RIN 0579–AE10

Importation of Phalaenopsis Spp. Plants for Planting in Approved Growing Media From China to the Continental United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations governing the importation of plants for planting to authorize the importation of *Phalaenopsis* spp. plants for planting from China in approved growing media into the continental United States, subject to a systems approach. The systems approach would consist of measures that are currently specified in the regulations as generally applicable to all plants for planting authorized importation into the United States in approved growing media. This proposed rule would allow for the importation of *Phalaenopsis* spp. plants for planting from China in approved growing media, while providing protection against the introduction of plant pests.

DATES: We will consider all comments that we receive on or before July 31, 2015.

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0106*.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS–2014–0106, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0106* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Lydia E. Colón, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1236; (301) 851–2302.

SUPPLEMENTARY INFORMATION:

Background

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

The regulations differentiate between prohibited articles and restricted articles. Prohibited articles are plants for planting whose importation into the United States is not authorized due to the risk the articles present of introducing or disseminating plant pests. Restricted articles are articles authorized importation into the United States, provided that the articles are subject to measures to address such risk.

Conditions for the importation into the United States of restricted articles in growing media are found in § 319.37–8. Within that section, the introductory text of paragraph (e) lists taxa of restricted articles that may be imported into the United States in approved growing media, subject to the provisions of a systems approach. Paragraph (e)(1) of § 319.37–8 lists the approved growing

media, while paragraph (e)(2) contains the provisions of the systems approach. Within paragraph (e)(2), paragraphs (i) through (viii) contain provisions that are generally applicable to all the taxa listed in the introductory text of paragraph (e), while paragraphs (ix) through (xi) contain additional, taxon-specific provisions.

Currently, *Phalaenopsis* spp. plants for planting from China are not authorized for importation into the United States in approved growing media. However, the Animal and Plant Health Inspection Service (APHIS) has received a request from the national plant protection organization (NPPO) of China to authorize the importation of *Phalaenopsis* spp. plants for planting in approved growing media into the continental United States.

In evaluating China's request, we prepared a pest risk assessment (PRA) and a risk management document (RMD). Copies of the PRA and the RMD may be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT** or viewed on the Regulations.gov Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov).

The PRA, titled ''Importation of *Phalaenopsis* spp. Orchid Plants in Approved Growing Media from China into the Continental United States; A Pathway-Initiated Pest Risk Assessment,'' analyzed the potential pest risk associated with the importation of *Phalaenopsis* spp. plants for planting in approved growing media into the continental United States from China.

The PRA identified four quarantine pests that could be introduced into the continental United States through the importation of *Phalaenopsis* spp. plants for planting from China in approved growing media:

- *Spodoptera litura,* tropical armyworm;
- *Thrips palmi,* melon thrips;
- *Cylindrosporium phalaenopsidis,* a pathogenic fungus that causes orchid black spot;
- *Lissachatina fulica,* the giant African snail.

The PRA determined that these four pests pose a medium risk of following the pathway of *Phalaenopsis* spp. plants for planting in approved growing media from China into the continental United States and having negative effects on U.S. agriculture.

Based on these risk ratings, the RMD, titled ''Importation of *Phalaenopsis* spp. Orchids in Approved Growing Media from China into the Continental United States,'' identifies the phytosanitary measures necessary to ensure the safe importation into the continental United States of *Phalaenopsis* spp. plants for planting in approved growing media from China. The RMD finds that the mitigations that are currently specified in paragraphs (e)(2)(i) through (e)(2)(viii) of § 319.37–8 and that are generally applicable to the importation of all restricted articles authorized importation into the United States in approved growing media will mitigate the risk associated with the importation *Phalaenopsis* spp. plants for planting in approved growing media from China into the continental United States.

Accordingly, we propose to amend the introductory text of paragraph (e) of § 319.37–8 to add *Phalaenopsis* spp. plants for planting from China to the list of taxa authorized importation into the United States in approved growing media. We also propose to add a paragraph (e)(2)(xii) to § 319.37–8 that would specify that such plants for planting may only be imported into the continental United States.

Executive Order 12866 and Regulatory Flexibility Act

This proposed 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. 603, we have performed an initial regulatory flexibility analysis, which is summarized below, regarding the economic effects of this proposed rule on small entities. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the Regulations.gov Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov).

Based on the information we have, there is no reason to conclude that adoption of this proposed rule would result in any significant economic effect on a substantial number of small entities. However, we do not currently have all of the data necessary for a comprehensive analysis of the effects of this proposed rule on small entities. Therefore, we are inviting comments on potential effects. In particular, we are interested in determining the number and kind of small entities that may incur benefits or costs from the implementation of this proposed rule.

APHIS is proposing to amend the regulations in 7 CFR 319.37–8(e) to authorize the importation from China into the continental United States of orchids of the genus *Phalaenopsis* established in an approved growing medium, subject to specified growing, inspection, and certification requirements.

Currently, only bare-rooted *Phalaenopsis* spp. plants for planting may be imported from China into the United States. Eliminating this restriction by allowing the importation of plants in growing media, as well as bare-rooted plants, is expected to increase the number and quality of orchids imported from China by U.S. producers, who then finish the plants for the retail market. This change could result in cost savings for these U.S. producers, which may or may not be passed on to U.S. buyers. The amended regulations could also result in the importation of market-ready *Phalaenopsis* spp. in approved growing media from China that would directly compete at wholesale and retail levels with U.S. finished potted orchids. The latter scenario is considered unlikely, given the technical challenges and additional marketing costs incurred when shipping finished plants in pots.

The Small Business Administration (SBA) small-entity standard for entities involved in Floriculture Production (NAICS 111422) is $750,000 or less in annual receipts. The number of entities participating in this broadly defined industry was 26,963 in 2012, with $5.9 billion in sales that year. Orchid producers numbered 177 in 2012, or 0.6 percent of the total industry. In 2013, the average wholesale value of orchids produced by the largest producers was $1.4 million. These businesses fall above the SBA threshold for small entities. However, this average sales value excludes sales by an unknown number of smaller establishments that qualify as small entities by the SBA definition.

While many of the U.S. entities that would be affected by the proposed rule such as orchid producers and importers may be small by SBA standards, we expect economic effects for these entities to be modest. We welcome informed public comment that would enable us to better determine the extent to which U.S. small entities may be affected positively or negatively by this proposed rule.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the importation of *Phalaenopsis* spp. plants in approved growing media from China into the continental United States, we have prepared an environmental assessment. The environmental assessment was 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 may be viewed on the Regulations.gov Web site or in our reading room. (A link to Regulations.gov and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this proposed rule.) In addition, copies may be obtained by calling or writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS–2014–0106. Please send a copy of your comments to: (1) Docket No. APHIS–2014–0106, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, Room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250.

APHIS is proposing to amend the plants for planting regulations to allow the importation of *Phalaenopsis* spp. plants for planting in approved growing media from China into the continental United States. As a condition of entry, the plantlets would have to be produced in accordance with a systems approach. This action would allow for the importation of *Phalaenopsis* spp. plants for planting from China into the continental United States in approved growing media while providing protection against the introduction of plant pests.

Allowing *Phalaenopsis* spp. plants for planting to be imported into the continental United States will require information collection activities, including phytosanitary certificates, inspections, agreements between producers and the NPPO of China, and an agreement between the NPPO of China and APHIS.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.,* permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 0.6956 hours per response.

Respondents: NPPO of China, producers, exporters.

Estimated annual number of respondents: 5.

Estimated annual number of responses per respondent: 4.6.

Estimated annual number of responses: 23.

Estimated total annual burden on respondents: 16 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the EGovernment Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

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 propose to amend 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.

■ 2. Section 319.37–8 is amended as follows:

■ a. In the introductory text of paragraph (e), in the entry for ''Phalaenopsis spp. from Taiwan'', by adding the words ''and the People's Republic of China'' after the word ''Taiwan''.

■ b. By adding a paragraph (e)(2)(xii).

The addition reads as follows:

§ 319.37–8 Growing media.

* * * * *

(e) * * *

(2) * * *

(xii) Plants for planting of *Phalaenopsis* spp. from the People's Republic of China may only be imported into the continental United States, and may not be imported or moved into Hawaii or the territories of the United States.

* * * * *

Done in Washington, DC, this 22nd day of May 2015.

Kevin Shea

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015–13162 Filed 5–29–15; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF ENERGY

10 CFR Part 429

[Docket No. EERE–2013–BT–NOC–0005]

Appliance Standards and Rulemaking Federal Advisory Committee: Notice of Open Meeting and Webinar

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

ACTION: Notice of open meeting and webinar.

SUMMARY: This notice announces a meeting of the Appliance Standards and Rulemaking Federal Advisory Committee (ASRAC). The Federal Advisory Committee Act requires that agencies publish notice of an advisory committee meeting in the **Federal Register**.

DATES: June 17, 2015, 9:00 a.m.–5:00 p.m.

ADDRESSES: U.S. Department of Energy, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, Room 8E–089. Individuals will also have the opportunity to participate by webinar. To register for the webinar and receive call-in information, please register *https://attendee.gotowebinar.com/register/5483145007578718466.*

FOR FURTHER INFORMATION CONTACT: John Cymbalsky, ASRAC Designated Federal Officer, U.S. Department of Energy (DOE), Office of Energy Efficiency and Renewable Energy, 950 L'Enfant Plaza SW., Washington, DC, 20024. Email: *asrac@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: Purpose of Meeting: To provide advice and recommendations to the Energy Department on the development of standards and test procedures for residential appliances and commercial equipment.

Tentative Agenda: (Subject to change; final agenda will be posted at *http://www.regulations.gov/#!docketDetail;D=EERE-2013-BT-NOC-0005*):

- Discussion and prioritization of topic areas that ASRAC can assist the Appliance and Equipment Standards Program.

Public Participation: Members of the public are welcome to observe the business of the meeting and, if time allows, may make oral statements during the specified period for public comment. To attend the meeting and/or to make oral statements regarding any of the items on the agenda, email *asrac@ee.doe.gov.* In the email, please indicate your name, organization (if appropriate), citizenship, and contact information. Please note that foreign nationals participating in the public meeting are subject to advance security screening procedures which require advance notice prior to attendance at the public meeting. If a foreign national wishes to participate in the public meeting, please inform DOE as soon as possible by contacting Ms. Regina Washington at (202) 586–1214 or by email: *Regina.Washington@ee.doe.gov* so that the necessary procedures can be completed. Anyone attending the meeting will be required to present a government photo identification, such as a passport, driver's license, or government identification. Due to the required security screening upon entry, individuals attending should arrive early to allow for the extra time needed.

Due to the REAL ID Act implemented by the Department of Homeland Security (DHS) recent changes regarding ID requirements for individuals wishing to enter Federal buildings from specific states and U.S. territories. Driver's licenses from the following states or territory will not be accepted for building entry and one of the alternate forms of ID listed below will be required.

DHS has determined that regular driver's licenses (and ID cards) from the following jurisdictions are not acceptable for entry into DOE facilities: Alaska, Louisiana, New York, American Samoa, Maine, Oklahoma, Arizona, Massachusetts, Washington, and Minnesota.

Acceptable alternate forms of Photo-ID include: U.S. Passport or Passport Card; an Enhanced Driver's License or Enhanced ID-Card issued by the states of Minnesota, New York or Washington (Enhanced licenses issued by these states are clearly marked Enhanced or Enhanced Driver's License); a military ID or other Federal government issued Photo-ID card.

Docket: The docket is available for review at *www.regulations.gov,* including **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials. All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

Issued in Washington, DC, on May 26, 2015.

Kathleen B. Hogan

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

[FR Doc. 2015–13101 Filed 5–29–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE–2011–BT–STD–0043]

Miscellaneous Refrigeration Products Working Group: Notice of Open Meetings and Webinar

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

ACTION: Notice of open meetings and webinars.

SUMMARY: This document announces a series of meetings of the Miscellaneous Refrigeration Products Working Group (MREF Working Group). The Federal Advisory Committee Act requires that agencies publish notice of an advisory committee meeting in the **Federal Register**.

DATES: See **SUPPLEMENTARY INFORMATION** section for meeting dates.

ADDRESSES: Unless otherwise specified in the **SUPPLEMENTARY INFORMATION** section, the meetings will be held at U.S. Department of Energy, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585. Individuals will also have the opportunity to participate by webinar. To register for the webinar and receive call-in information, please register *https://attendee.gotowebinar.com/register/6152385849392379138.*

FOR FURTHER INFORMATION CONTACT: John Cymbalsky, ASRAC Designated Federal Officer, U.S. Department of Energy (DOE), Office of Energy Efficiency and Renewable Energy, 950 L'Enfant Plaza, SW., Washington, DC 20024. Email: *asrac@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: The meetings will be held:

- June 11–12, 2015;
- July 15–16, 2015;
- August 11–12, 2015; and
- August 18–19, 2015;

The first day of each meeting series will take place from 9:00 a.m. to 5:00 p.m. (EDT). The second day will take place from 8:00 a.m. to 4:00 p.m. (EDT).

Members of the public are welcome to observe the business of the meeting and, if time allows, may make oral statements during the specified period

for public comment. To attend the meeting and/or to make oral statements regarding any of the items on the agenda, email *asrac@ee.doe.gov.* In the email, please indicate your name, organization (if appropriate), citizenship, and contact information. Please note that foreign nationals participating in the public meeting are subject to advance security screening procedures which require advance notice prior to attendance at the public meeting. If a foreign national wishes to participate in the public meeting, please inform DOE as soon as possible by contacting Ms. Regina Washington at (202) 586–1214 or by email: *Regina.Washington@ee.doe.gov* so that the necessary procedures can be completed. Anyone attending the meeting will be required to present a government photo identification, such as a passport, driver's license, or government identification. Due to the required security screening upon entry, individuals attending should arrive early to allow for the extra time needed.

Due to the REAL ID Act implemented by the Department of Homeland Security (DHS) recent changes regarding ID requirements for individuals wishing to enter Federal buildings from specific states and U.S. territories. Driver's licenses from the following states or territory will not be accepted for building entry and one of the alternate forms of ID listed below will be required.

DHS has determined that regular driver's licenses (and ID cards) from the following jurisdictions are not acceptable for entry into DOE facilities: Alaska, American Samoa, Arizona, Louisiana, Maine, Massachusetts, Minnesota, New York, Oklahoma, and Washington.

Acceptable alternate forms of Photo-ID include: U.S. Passport or Passport Card; an Enhanced Driver's License or Enhanced ID-Card issued by the states of Minnesota, New York or Washington (Enhanced licenses issued by these states are clearly marked Enhanced or Enhanced Driver's License); a military ID or other Federal government issued Photo-ID card.

Docket: The docket is available for review at *www.regulations.gov,* including **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials. All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

Issued in Washington, DC, on May 26, 2015.

Kathleen B. Hogan,

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

[FR Doc. 2015–13139 Filed 5–29–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–0787; Directorate Identifier 2015–NE–10–AD]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney Division Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Pratt & Whitney Division (PW) PW4164, PW4168, PW4168A, PW4164C, PW4164C/B, PW4164–1D, PW4168–1D, PW4168A–1D, PW4170, PW4164C–1D, PW4164C/B–1D, PW4050, PW4052, PW4056, PW4060, PW4060A, PW4060C, PW4062, PW4062A, PW4152, PW4156, PW4156A, PW4158, PW4160, PW4460, PW4462, and PW4650 turbofan engines with a low-pressure turbine (LPT) 4th stage inner air seal (IAS), P/N 51N038, installed. This proposed AD was prompted by the discovery, during routine overhaul of the LPT, of cracks in the barrel section of the 4th stage IAS. This proposed AD would require removal of the LPT 4th stage IAS, P/N 51N038, according to a prescribed schedule. We are proposing this AD to prevent failure of the LPT 4th stage IAS, which could lead to an uncontained IAS release, damage to the engine, and damage to the airplane.

DATES: We must receive comments on this proposed AD by July 31, 2015.

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 Pratt & Whitney Division, 400 Main St., East Hartford, CT 06108; phone: (860) 565–8770; fax: (860) 565–4503. You may view this 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* by searching for and locating Docket No. FAA–2015–0787; 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: Katheryn Malatek, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7747; fax: 781–238–7199; email: *katheryn.malatek@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–2015–0787; Directorate Identifier 2015–NE–10–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 propose to adopt a new AD for all PW PW4164, PW4168, PW4168A, PW4164C, PW4164C/B, PW4164–1D, PW4168–1D, PW4168A–1D, PW4170,

PW4164C–1D, PW4164C/B–1D, PW4050, PW4052, PW4056, PW4060, PW4060A, PW4060C, PW4062, PW4062A, PW4152, PW4156, PW4156A, PW4158, PW4160, PW4460, PW4462, and PW4650 turbofan engines with an LPT 4th IAS, P/N 51N038, installed. This proposed AD was prompted by 9 occasions of discovering, during routine overhaul of the LPT, cracks in the barrel section of the 4th stage IAS. This condition, if not corrected, could result in uncontained IAS release, damage to the engine, and damage to the aircraft. This proposed AD would require removal of the 4th stage IAS, P/N 51N038, according to a prescribed schedule. We are proposing this AD to prevent failure of the LPT 4th stage IAS, which could lead to an uncontained IAS release, damage to the engine, and damage to the airplane.

Related Service Information

We reviewed PW Alert Service Bulletin (ASB) No. PW4G–100–A72–254, dated December 12, 2014. The ASB describes procedures and timetables for removing the LPT 4th stage IAS. This service information is reasonably available; see **ADDRESSES** for ways to access this service information.

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 removal of the LPT 4th stage IAS, P/N 51N038, according to a prescribed schedule.

Differences Between This Proposed AD and the Service Information

PW ASB No. PW4G–100–A72–254, dated December 12, 2014, applies to certain PW4000 engine models. This proposed AD applies to the 7 engine models listed in the ASB, plus 4 additional PW4000 engine models certificated for use in the U.S. for which the affected LPT 4th IAS, P/N 51N038, is eligible for installation. These 11 engine models are listed in paragraph (c)(1) of this AD.

We further expanded the applicability to cover 16 additional engine models, listed in paragraph (c)(2) of this AD, which are prohibited from installing P/N 51N038, if that part was ever installed on any engine listed in paragraph (c)(1) of this AD. The unsafe condition described in paragraph (d) of this AD could exist in the part if it was ever operated in any engine listed in paragraph (c)(1) of this AD.

Costs of Compliance

We estimate that this proposed AD affects 72 engines installed on airplanes of U.S. registry. We also estimate that 9 of the engines would require replacement parts during shop visit, and that for these engines the pro-rated replacement parts cost would be $23,805 per engine, and compliance with this proposed AD would require about 49 hours of labor per engine. The average labor rate is $85 per hour. We also estimate that 63 of the engines would require replacement parts during LPT overhaul, that the prorated replacement parts cost for these 63 engines would be $43,545 per engine, and that compliance with this proposed AD for these 63 engines would require 0 additional hours of labor per engine since the parts are already exposed during LPT overhaul. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $2,995,065.

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 to the extent that it justifies making a regulatory distinction, and

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

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):

Pratt & Whitney Division: Docket No. FAA–2015–0787; Directorate Identifier 2015–NE–10–AD.

(a) Comments Due Date

We must receive comments by July 31, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to:

(1) All Pratt & Whitney Division (PW) PW4164, PW4168, PW4168A, PW4164C, PW4164C/B, PW4164–1D, PW4168–1D, PW4168A–1D, PW4170, PW4164C–1D, and PW4164C/B–1D turbofan engines with a low-pressure turbine (LPT) 4th stage inner air seal (IAS), part number (P/N) 51N038, installed.

(2) All PW4050, PW4052, PW4056, PW4060, PW4060A, PW4060C, PW4062, PW4062A, PW4152, PW4156, PW4156A, PW4158, PW4160, PW4460, PW4462, and PW4650 turbofan engines with an LPT 4th stage IAS, P/N 51N038, installed.

(d) Unsafe Condition

This AD was prompted by the discovery, during routine overhaul of the LPT, of cracks in the barrel section of the 4th stage IAS which could, if not corrected, result in uncontained IAS release, damage to the engine, and damage to the aircraft. We are issuing this AD to prevent failure of the LPT 4th stage IAS, which could lead to an uncontained IAS release, damage to the engine, and damage to the airplane.

(e) Compliance

Comply with this AD within the compliance times specified, unless already done. For the engines listed in paragraph (c)(1) of this AD:

(1) At each LPT overhaul after the effective date of this AD remove from service the LPT 4th stage IAS, P/N 51N038.

(2) At each engine shop visit after the effective date of this AD, remove from service the LPT 4th stage IAS, P/N 51N038, if it has more than 10,900 cycles since new.

(f) Installation prohibition

(1) Do not install any LPT 4th stage IAS, P/N 51N038, with more than 0 flight cycles on any engine listed in paragraph (c)(1) of this AD.

(2) Do not install on any engine listed in paragraphs (c)(2) of this AD, any LPT 4th stage IAS, P/N 51N038, which was previously installed on any engine listed in paragraph (c)(1) of this AD.

(g) Definitions

For the purposes of this AD:

(1) An LPT overhaul is defined as maintenance which involves disassembly of the LPT rotor module.

(2) An ''engine shop visit'' is the induction of an engine into the shop for maintenance involving the separation of pairs of major mating engine flanges (lettered flanges). The separation of engine flanges solely for the purpose of transportation without subsequent engine maintenance does not constitute an engine shop visit.

(h) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE–AD–AMOC@faa.gov.*

(i) Related Information

(1) For more information about this AD, contact Katheryn Malatek, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7747; fax: 781–238–7199; email: *katheryn.malatek@faa.gov.*

(2) PW Alert Service Bulletin No. PW4G–100–A72–254, dated December 12, 2014, can be obtained from PW using the contact information in paragraph (i)(3) of this AD.

(3) For service information identified in this AD, contact Pratt & Whitney Division, 400 Main St., East Hartford, CT 06108; phone: (860) 565–8770; fax: (860) 565–4503.

(4) You may view this 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.

Issued in Burlington, Massachusetts, on May 13, 2015.

Colleen M. D'Alessandro,

Assistant Directorate Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2015–12663 Filed 5–29–15; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2015–0223; FRL–9928–53–Region 7]

Approval and Promulgation of Air Quality Implementation Plans; Missouri; 2013 Missouri State Implementation Plan for the 2008 Lead Standard

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) proposes to grant full approval of Missouri's attainment demonstration State Implementation Plan (SIP) for the 2008 lead National Ambient Air Quality Standard (NAAQS) nonattainment of the Viburnum Trend area in portions of Iron, Dent and Reynolds Counties, Missouri, submitted on April 18, 2013. EPA believes that the SIP submitted by the State satisfies the applicable requirements of the Clean Air Act (CAA) identified in EPA's Final Rule published on October 15, 2008, and will bring the area into attainment of the 0.15 microgram per cubic meter (ug/m^3) lead NAAQS in the Viburnum Trend, Missouri area.

In this action, EPA also proposes approval of a revision to the Missouri SIP to incorporate an amendment to an existing Missouri statute to restrict lead emissions from specific sources. The amendment revises certain throughput and emissions limits applicable to the Doe Run Buick Resource Recycling Facility (BRRF) in the Viburnum Trend lead nonattainment area. Approval of this rule will ensure consistency between the state and Federally-approved rules, and ensure Federal enforceability of the revised state rule. This revision was submitted to EPA on October 30, 2009.

DATES: Comments must be received on or before July 1, 2015

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2015–0223, by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.

2. *Email: doolan.stephanie@epa.gov.*

3. *Mail, Hand Delivery or Courier:* Stephanie Doolan, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219.

Instructions: Direct your comments to Docket ID No. EPA–R07–OAR–2015–0223. 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, *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 *www.regulations.gov* or in hard copy at the EPA, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas. EPA requests that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The interested persons wanting to examine these documents should make an appointment with the office at least 24 hours in advance.

FOR FURTHER INFORMATION CONTACT: Stephanie Doolan at (913) 551–7719, or by email at *doolan.stephanie@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' or ''our'' refer to EPA.

Table of Contents

I. What is being addressed in this document?

In this document, EPA is addressing Missouri's attainment demonstration SIP for the 2008 lead NAAQS nonattainment in the Viburnum Trend Missouri area. The applicable standard addressed in this action is the lead NAAQS promulgated by EPA in 2008. EPA believes that the SIP submitted by the state satisfies the applicable requirements of the CAA identified in EPA's Final Rule (73 FR 66964, October 15, 2008), and will bring the area into attainment of the 0.15 microgram per cubic meter (ug/m^3) lead NAAQS in the Viburnum Trend lead nonattainment area.

In this action, EPA is also addressing a revision to the Missouri SIP to approve portions of a revision to the State of Missouri Code of State Regulations (CSR) 10–6.120, ''Restriction of Emissions of Lead from Specific Lead Smelter-Refinery Installations''. This revision pertains to throughput limits applicable to the BRRF, which is the primary source of lead emissions in the Viburnum Trend nonattainment area. Pursuant to a withdrawal request from Missouri,[1] EPA is taking action on specific portions Missouri rule 10 CSR 6.120. Missouri rule 10 CSR 6.120, as it pertains to the Buick Resources Recycling Facility, was previously approved in the Missouri SIP. *See* 69 FR 51953. The Viburnum Trend SIP addressed in this proposed action relies upon portions of the revision to 10 CSR 6.120.

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

The state submission has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. The submission also satisfied the completeness criteria of 40 CFR part 51, appendix V. In addition, the revision meets the substantive SIP requirements of the CAA, including section 110 and implementing regulations.

III. What action is EPA taking?

EPA is proposing to grant full approval of Missouri's attainment demonstration SIP for the 2008 lead NAAQS. We are also proposing to approve portions of a revision to Missouri rule 10 CSR 6.120, ''Restriction of Emissions of Lead from Specific Lead Smelter-Refinery Installations''. EPA is proposing this action in order to solicit comments. Final rulemaking will occur after consideration of any comments received.

IV. Background

EPA established the NAAQS for lead on October 5, 1978 (43 FR 46246). The 1978 NAAQS for lead is set at a level of 1.5 micrograms per cubic meter (ug/m^3) of air, averaged over a calendar quarter. The Viburnum Trend area is designated as attainment for the 1978 lead NAAQS.

On October 15, 2008, EPA established a new lead NAAQS of 0.15 ug/m^3 in air, measured as a rolling three-month average. (73 FR 66964). On November 22, 2010, the Buick/Viburnum Trend area was designated as nonattainment for the 2008 lead NAAQS. (75 FR 71033).[2] Under sections 191(a) and 192(a) of the CAA, Missouri is required to submit to EPA an attainment demonstration SIP revision for lead and to demonstrate the nonattainment area will reach attainment of the 2008 lead NAAQS no later than five years from the date of the nonattainment area designation.

Missouri rule 10 CSR 10–6.120 ''Restriction of Emissions of Lead from Specific Lead Smelter—Refinery Installations'' establishes lead stack emissions limits and testing and recordkeeping requirements at specific lead smelters including the Herculaneum facility[3] in Herculaneum, Missouri, and BRRF in Boss, Missouri. The Buick/Viburnum Trend lead NAAQS attainment SIP relies upon the requirements imposed by Missouri rule 10 CSR 10–6.120, with the exception of those requirements withdrawn by Missouri. In addition, the approval of the production limits for BRRF relies upon the modeling demonstration proposed in the Viburnum Trend area lead NAAQS attainment SIP, therefore, approval of the two SIP revisions are proposed concurrently herein.

V. Technical Review of the Attainment Demonstration SIP Related to the 2008 Lead NAAQS

A. Facility Description

1. BRRF Process Description

There are four lead-emitting sources contributing to the Buick/Viburnum Trend lead nonattainment area: BRRF; the Buick Mine and Mill; the Casteel Mine; and K & D Crushing. BRRF operates as a secondary smelter of lead, lead-containing materials including spent lead acid batteries, lead bullets and shot, lead-containing glass from cathode ray tubes, and lead-based paint chips from lead abatement projects. The Buick Mine and Mill, located to the south of BRRF, conducts subsurface mining and ore processing. The Casteel Mine, located to the north of BRRF, also conducts subsurface mining. K & D Crushing, also located to the north of BRRF, conducts ore crushing at the surface of the Casteel Mine. Crushed and concentrated lead-containing ore was formerly processed at the Herculaneum primary lead smelter, but since that facility ceased primary lead smelting in December 2013, the ore gets shipped out of the U.S. for overseas processing.

As stated above, BRRF is located in the Buick/Viburnum Trend nonattainment area. BRRF's production limit is limited to 175,000 tons of total lead production each year pursuant to Missouri Rule 10 CSR 6.120(3)(B)2. The majority of the lead recycled by BRRF is from spent automotive and industrial batteries.

Lead-bearing items, primarily post-consumer lead-acid batteries, arrive at

[1] See email from Wendy Vit, Air Quality Planning Section Chief for the Missouri Department of Natural Resources, to Michael Jay, Chief of Atmospheric Programs Section, Air Planning and Development Branch of EPA Region 7, dated March 4, 2015, available in the Docket.

[2] EPA also designated city of Herculaneum, Missouri, as nonattainment for the 2008 lead NAAQS. 75 FR 71033. This nonattainment area has been addressed in a separate action. 79 FR 62574.

[3] The former Herculaneum primary lead smelter ceased lead smelting operations on December 31, 2013, pursuant to the terms of the Consent Decree applicable to the Herculaneum facility entered into by Doe Run, Missouri, and EPA in the United States District Court in the Eastern District of Missouri, Case No. 4:10–cv–01895–JCH (2011 Consent Decree) on December 21, 2011.

the facility by truck. Spent batteries are stored in a battery bunker until processed in a shredder. Battery acid (weak sulfuric acid) is drained during shredding, collected in storage tanks and neutralized using calcium hydroxide. The shredded batteries are placed in a vibrating feeder in route to a conveyor belt to the hammer mill. The hammer mill pounds the material into smaller pieces.

Batteries contain metal grids, lead posts, plastic casing and other components, separators and lead sulfate paste. The paste is removed by washing through a set of screens for further processing. The batteries further undergo a separation process under which lead and metal parts are separated from the plastic and other debris. The lead and metal parts are primarily fed to the reverberatory furnace, but also may be fed to the blast furnace. The plastic and other debris are skimmed off and sent to recycling facilities.

The lead sulfate paste is passed through a filter press and neutralized with hydrated lime to form calcium sulfate, then heated at extremely high temperatures in the reverberatory furnace to produce soft antimonial lead bullion and reverberatory slag. Sulfur emissions from the reverberatory furnace are controlled by a dry, flue gas desulfurization scrubber that introduces lime and water to the reverberatory flue gas in a reaction and forms gypsum, which is removed from the gas stream by a polishing baghouse. The reverberatory slag is fed to the blast furnace to recover the antimonial lead. The Missouri SIP submittal contains a process flow diagram that details the emission point sources throughout the process that were included in the modeling.

2. Mines/Mills Process Description

Modeling analysis conducted by Missouri determined that the Buick Mine and Mill, the Casteel Mine, and the K & D Crushing operations contribute significantly to the monitored violation of the 2008 Lead NAAQS at the air monitor. There are other mining and milling operations in the Viburnum Trend area, but these operations were not found to contribute significantly to the Lead NAAQS violation. Emissions from the Doe Run mining and milling operations are primarily in the form of fugitives from the processing of lead containing rock until it becomes a wet concentrate that is shipped to other customers. The process is described in greater detail as follows.

Mining begins with the subsurface drilling and blasting of dolomite rock which contains varying amounts of lead sulfide, zinc sulfide, and copper-iron sulfide minerals. At the Casteel mine, the ore is hauled to the skip pocket ''as blasted,'' with no underground crushing. At the surface, the coarse ore is crushed by K & D Crushing, a contractor to Doe Run, into smaller pieces. The crushed ore is hauled to other Doe Run facilities, most frequently to the Buick Mine and Mill.

At the Buick Mine and Mill, ore is hauled from the active mining faces to a central crusher where it is crushed down to approximately eight inch pieces. The ore is hoisted to the surface then conveyed to further on-site crushing and screening operations. After being crushed aboveground to less than 5/8-inch in size, the ore subjected to wet milling, and grinding with rods and ball mills until a coarse powder in a wet slurry is produced. The wet slurry further undergoes wet cyclone and floatation separation into lead sulfide, zinc sulfide and copper sulfide components.

The concentrated sulfides further undergo dewatering to produce a concentrate that formerly was shipped to the Herculaneum primary lead smelter. As stated above, the Herculaneum facility ceased operations smelting operations in December 2013; thus, the concentrate is shipped overseas to primary lead smelting operations or to other customers.

B. Model Selection, Meteorological and Emissions Inventory Input Data

Missouri conducted air dispersion modeling to evaluate the effectiveness of the proposed control strategy. The model, AERMOD, was utilized and is EPA's preferred model for demonstrating attainment of the lead NAAQS. AERMOD estimates the combined ambient impact of sources by simulating Gaussian dispersion of emissions plumes. Emission rates, wind speed and direction, atmospheric mixing heights, terrain, plume rise from stack emissions, initial dispersion characteristics of fugitive sources, particle size and density are all factors considered by the model when estimating ambient impacts. Missouri performed two dispersion modeling analyses for the 2008 lead NAAQS for the Viburnum Trend nonattainment area. One was an analysis of current conditions to ensure the model is performing adequately (base case). The second analysis examined the effectiveness of proposed emission controls (future case). The results of these analyses will be discussed in more detail in section V.C. of this document.

Missouri used the meteorological data from the meteorological monitoring station approximately 0.8 miles south of BRRF, co-located with the Buick South non-ambient lead air quality monitor. EPA's preference is for the use of five years of meteorological data to input the model (40 CFR part 51, appendix W, section 8.3.1.2); however, a minimum of one year of representative meteorological data are required. A detailed analysis of the meteorological data collected on-site concluded that only one consecutive year, from August 2009 to July 2010, met the data quality requirements; thus, these surface level data were used to input the model. Wind speed and direction data from the on-site meteorological station were used to input the model, and surface temperature, humidity, and other information from the Farmington, Missouri, National Weather Service observation site were added to the BRRF wind observations. Finally, upper air data from the station at National Weather Service site in Springfield, Missouri, were used to input the model for the parameters including vertical temperature, moisture and wind characteristics of the atmosphere. This data set provided confidence that the controls selected for the attainment demonstration will be effective over a large variety of meteorological conditions. The meteorological data were run through AERMOD's pre-processors to make the data usable by the model.

As required by section 172(c)(3) of the CAA, a revised emission inventory was developed for this nonattainment area. Hourly emissions data from January 2009 to October 2010 from BRRF and the Buick Mine and Mill were used to model the base case. Beginning in late 2010, construction of emission control projects to control fugitive lead dust and sulfur dioxide (SO_2) impacted the base case emissions and ambient air monitoring data, making them no longer representative of pre-control conditions. Emissions represented in the model are from release points, stack emissions validated by stack test data, and fugitive emissions calculated using field measurements wherever possible or estimated based on EPA's AP–42 guidelines.[4]

The 2011 lead emission totals for Viburnum Trend nonattainment area are listed in Table 1 below. As discussed above, the emissions from the other mine and mill operations in the Viburnum Trend area were not found to

[4] AP–42, Compilation of Air Pollutant Emission Factors, Fifth Edition, *http://www.epa.gov/ttnchie1/ap42/.*

significantly impact the lead concentrations reported at the violating ambient air monitor and therefore are not listed.

Facility name	Site name	2011 Emissions [a] tons per year (tpy)
BRRF	Buick Smelter	16.87
Doe Run	Buick Mine and Mill	1.07
Doe Run	Casteel Mine	0.2
K & D Crushing	Casteel Mine	0.2
Total Emissions		18.34

[a] Emissions reported to the Missouri Emissions Inventory System (MoEIS) database which are reported to EPA's National Emissions Inventory (NEI) database, version 1, released September 30, 2013, found at *http://www.epa.gov/ttnchie1/net/2011inventory.html.*

In accordance with 40 CFR part 51, appendix W, background concentrations must be considered when determining NAAQS compliance. Background concentrations are intended to include impacts attributable to natural sources, nearby sources (excluding the dominant source(s)), and unidentified sources. The calculated background concentration includes all sources of lead not already included in the model run script. The background concentration includes distant sources of lead, which may have originally derived from the mining and milling and smelting operations, or naturally occurring lead in soils that has become re-entrained in the atmosphere.

In general, the background value is calculated by averaging the monitored concentrations at monitor sites outside the area of immediate dominant source impact and on days when the predominant wind direction was not blowing from the dominant source to the monitors. Missouri began with all monitored days and identified days with no measured one-hour average wind direction from the smelter. Each monitor was examined in conjunction with an acceptable wind fan and the concentrations are averaged on days with no predominant winds from the dominant sources. The monitor site chosen for the background determination is the Oates monitor located 4.9 miles south of BRRF. The days selected for the calculation match the model study period.

EPA conducted an independent analysis of the data from the Oates monitor and corresponding wind direction to verify the background concentration calculated by Missouri. Based on its independent analysis, EPA agrees that the calculated value represents a conservative estimate of background during the study period. Additional information can be found in the Missouri SIP, Section 4.3.

C. Modeling Results

1. Base Case Analysis

As discussed above, Missouri used the AERMOD dispersion model to run two analyses, the base case and the future case. The base case evaluated a reasonable estimate of maximum potential emissions to account for contributing sources based on normal facility operations. The base case model analysis used monitoring, emissions and meteorological data from August 2009 through July 2010.

Results from the base case modeling were compared with actual monitoring data from the same time period to examine the reliability of the model. The statistical analysis was conducted using the coefficient of correlation, or R^2. The correlation between modeling outputs under the base case and monitoring data was 0.8551 or greater, with 1.0 indicating 1:1 correlation, confirms the accuracy and reliability of the model's inputs and results. EPA agrees with Missouri's determination that the model is sufficiently reliable to predict that the control measures modeled in the attainment demonstration (see paragraph 5.C.2 Future Case Analysis below) will result in monitored values below the 2008 Lead NAAQS.

2. Future Case Analysis

The future case analysis evaluated the control strategies of the 2013 SIP revision pursuant to the existing Federally enforceable requirements that are applicable to the facility as well as the enforceable 2013 Consent Judgment between Missouri, BRRF and Doe Run. *See* appendix M, Missouri SIP. The future case dispersion modeling is the attainment demonstration used to verify that the proposed control strategies will bring the Buick/Viburnum Trend lead nonattainment area into compliance with the 2008 lead NAAQS.

The differences between the base and future case emissions rates are based on the changes to the operations resulting from implementation of the control measures required by the 2013 Consent Judgment. The control measures are discussed in paragraph V.D, Control Strategy, below.

Many of the emissions reduction projects that are necessary to meet the 2008 Lead NAAQS were also required to be implemented by January 6, 2014, for compliance with the National Emissions Standard for Hazardous Air Pollutants (NESHAP) for Secondary Lead Smelting (77 FR 556, January 5, 2012). The Secondary Lead NESHAP, applicable to BRRF, requires, among other things, total enclosure and ventilation of lead processing and handling buildings to a negative pressure requirement of 0.02 millimeters of mercury (mm Hg) and housekeeping procedures to reduce fugitive lead-containing dust.

The secondary lead NESHAP, as fully implemented, is expected to result in a building capture efficiency of approximately 95 percent. EPA has allowed facilities to assume, on a site-specific basis, a building fugitive capture efficiency of greater than 95 percent upon demonstration that control measures exceed the requirements of the secondary lead NESHAP. In the case of BRRF, upon careful consideration of site-specific control measures, including the use of local exhaust ventilation devices (LEVs) and a demonstrated negative pressure in buildings exceeding 0.02 mm Hg, EPA agreed with Missouri that a building fugitives capture efficiency of 98 percent was appropriate to use in the modeling. This assumed 98 percent building capture efficiency impacts the modeled emissions rates as well as the estimated emissions reductions described in paragraph V.D, Control Strategy, below. A more detailed discussion of the building fugitives capture efficiency discussion may be found in section 6.2 of Missouri's SIP revision.

The emissions rate reductions are expected to result in a monitored three-

month rolling average of 0.128 μg/m^3 lead or less at the nearest ambient monitoring location. When added to the background concentration of 0.20 μg/m^3, the predicted maximum three-month rolling average lead concentration is 0.148 μg/m^3. By comparison, the 2008 Lead NAAQS is 0.150 μg/m^3. Therefore, Missouri's modeling demonstrates attainment of the standard.

EPA conducted an independent analysis to verify the predictions of Missouri's modeling. EPA agrees with the modeling conducted by Missouri for its future case analysis.

D. Control Strategy

In order to bring the Viburnum Trend Area into attainment of the 2008 Lead NAAQS, Missouri developed and modeled a control strategy for point source (*e.g.,* stack) and fugitive emissions from the four significant sources of lead in the nonattainment area. Section 5.1 of the Missouri SIP revision details the control measures and the estimated emissions reductions.

Missouri, Doe Run and BRRF developed a Consent Judgment, found in the Missouri attainment demonstration SIP, appendix M, as a means to establish enforceable emission limits, controls, operating parameters, and contingency measures to reduce lead emissions from point, area, and fugitive lead dust sources in support of achieving attainment of the 2008 lead NAAQS as soon as practicable. The 2013 Consent Judgment was submitted as part of Missouri's SIP for the 2008 lead NAAQS.

A brief description of the BRRF control measures and anticipated emissions reductions is as follows.

a. By February 4, 2013, install a baghouse at the south refinery; this project is expected to reduce emissions by 98 percent.

b. By February 4, 2013, relocate a baghouse from the sweat furnace to the blast furnace storage feed building; this project is expected to reduce emissions by 80 percent by totally enclosing the blast furnace feed material storage and handling, while emissions from the main stack will experience a slight increase from the relocation.

c. By February 4, 2013, remove the rotary melter at the north refinery and connection of its baghouse to the north refinery process ducts; this represents an estimated 95 percent reduction in emissions from the previous process configuration.

d. By February 4, 2013, install a truck tire wash system for outbound traffic; washing trucks is anticipated to reduce fugitive emissions by 95 percent.

e. By February 4, 2013, install a pulse-jet baghouse to improve reverberatory furnace process ventilation; this project is expected to reduce reverberatory stack emissions by 45 percent and fugitives by 98 percent.

f. By February 4, 2013, install a dry lime SO_2 scrubber to further process gases as they exit the pulse-jet baghouse; this measure is intended to control SO_2, but will also reduce lead-containing particulates.

g. By January 6, 2014, enclose the refinery, blast furnace, reverberatory furnace and dross plant buildings and install a baghouse to achieve the negative pressure requirement of the Secondary Lead Smelting MACT (40 CFR 63, subpart X); the estimated reduction in overall emissions from these enclosures is expected to by 98 percent.

h. By December 31, 2013, install a 40-foot extension on the breaking separation and neutralization scrubber stack; the elevated stack height provides no net emissions decrease, but rather, greater dispersion of lead emissions that decreases the impact upon receptors within the nonattainment area.

i. By December 31, 2013, construct a 30,000 square foot building extension to the existing blast feed storage building enclosure; the estimated emissions reduction is included in item a. above.

j. By October 31, 2014, install ''batwing'' style ventilation covers to improve LEV capture efficiencies on refinery kettles; these covers contribute to the 98 percent emissions reduction in item g. above.

k. By December 31, 2013, install quick closing powered doors at the north refinery warehouse, south refinery warehouse, and the entrance to the reverberatory feed storage building; this measure also contributes to the 98 percent reduction in fugitives estimated for item g. above.

These projects have all been completed.

In addition to the control strategies required by the 2013 Consent Judgment, BRRF developed a baghouse Standard Operating Procedure (SOP) and a Work Practice Manual (WPM) to minimize lead emissions from operation and maintenance of all baghouses and to minimize fugitive dust emissions, respectively. The baghouse SOP is required by the Secondary Lead NESHAP and the WPM is required by both the Secondary Lead NESHAP and the Missouri rule 10 CSR 10–6.120. On December 18, 2012, (see appendix J of Missouri's SIP revision) Missouri approved these documents. Although the baghouse SOP and WPM were prepared for compliance with the Secondary Lead NESHAP, and Missouri rule 10 CSR 10–6.120, the activities required therein support the attainment of the 2008 Lead NAAQS as well.

The following is a list of the control measures required by Missouri's 2013 Consent Judgment for the Buick Mine and Mill, and the Casteel Mine. These control measures were implemented by Doe Run on or before June 1, 2013.

a. Modify Buick Mine updraft vents 1, 2, 3 and 6 to achieve a vertical release, defined as 45 degrees from horizontal or greater; this measure improves the dispersion of lead-containing particulates.

b. Preclude public access at the Casteel Mine at a minimum distance provided for in the 2013 Consent Judgment.

c. Preclude public access at Buick Mine updraft vents 1, 2, 3 and 6 at a minimum distance prescribed by the Consent Judgment.

d. Preclude access to the Buick Mine and Mill at a minimum distance prescribed by the 2013 Consent Judgment.

The 2011 Consent Decree between EPA, Missouri and Doe Run also requires enclosure of existing lead-containing material storage areas, interior lead concentrate conveyors, lead filtering system and associated equipment, lead concentrate storage stockpile, and the truck loading area and scale at the Buick Mine and Mill. This project was completed on or before September 1, 2013.

Based on EPA's analysis of the attainment modeling and its outcomes, EPA believes that Missouri's control strategy implemented pursuant to the 2013 Consent Judgment will bring the Viburnum Trend area into attainment of the 2008 Lead NAAQS.

E. Reasonably Available Control Measures (RACM) Including Reasonably Available Control Technology (RACT) and Reasonable Further Progress (RFP)

Section 172(c)(1) of the CAA requires nonattainment areas to implement all RACM, including emissions reductions through the adoption of Reasonably Available Control Technologies (RACT), as expeditiously as practicable. EPA interprets this as requiring all nonattainment areas to consider all available controls and to implement all measures that are determined to be reasonably available, except that measures which will not assist the area to more expeditiously attain the standard are not required to be implemented.[5] In March 2012, EPA

[5] See 58 FR 67751, December 22 1993, for a discussion of this interpretation as it relates to lead.

issued guidance titled, ''Implementation of Reasonably Available Control Measures (RACM) for Controlling Lead Emissions'' (RACM Guidance).[6]

Section 172(c)(2) of the CAA requires areas designated as nonattainment for criteria pollutants to include a demonstration of Reasonable Further Progress (RFP) in attainment demonstrations. Section 171(1) of the CAA defines RFP as annual incremental reductions in emissions of the relevant air pollutants as required by part D, or emission reductions that may reasonably be required by EPA to ensure attainment of the applicable NAAQS by the applicable date. Part D does not include specific RFP requirements for lead.

Missouri performed a RACM analysis in compliance with the RACM Guidance. As stated in the final lead NAAQS rule, RFP is satisfied by the strict adherence to a compliance schedule which is expected to periodically yield significant emission reductions. Missouri has determined that existing controls and practices, combined with additional controls and practices required by the 2013 Consent Judgment, constitute RACM. The control measures have been modeled and demonstrated to achieve the lead NAAQS and also comply with RACM and RFP.

In accordance with the Consent Judgment, all of the control measures for BRRF and the mines and mills have been installed to date. The secondary lead NESHAP requires BRRF to comply with control measures and work practices on or before January 6, 2014. Further, Missouri rule 10 CSR 10–6.120 requires BRRF to implement the WPM and places production limits on the facility. Collectively, these control measures and practices exceed the requirements of EPA's RACT Guidance.

RFP is addressed by the control strategy occurring in a timeframe consistent with the CAA and the 2013 Consent Judgment. Upon implementation of the control strategy and practices described above, ambient air quality concentrations are expected to drop at or below attainment levels immediately after implementation of the control strategy. Air monitoring data indicate that all of the nonattainment area's ambient air quality monitors reported lead (Pb) concentrations below the 2008 lead NAAQS for the three-month rolling average for February through May 2014. See *http://www.dnr.mo.gov/env/apcp/docs/leadmonitordata.pdf.* For the rolling calendar quarter of April through June 2014, and May through July, the Buick North monitor violated the NAAQS due to a power outage on June 22, 2014, that impacted air pollution control equipment. This violation did not trigger contingency measures because the 2013 Consent Judgment does not require the facility to begin monitoring attainment of the lead NAAQS until the rolling calendar quarter following installation of all control measures, which is November 2014 through January 2015. For the rolling calendar quarters starting in July through December 2014, the facility is attaining the lead NAAQS.

EPA proposes to approve Missouri's SIP as meeting sections 172(c)(1) and (c)(2) of the CAA.

F. Attainment Demonstration

CAA section 172 requires a state to submit a plan for each of its nonattainment areas that demonstrates attainment of the applicable ambient air quality standard as expeditiously as practicable, but no later than the specified attainment date. This demonstration should consist of four parts: (1) Technical analyses that locate, identify, and quantify sources of emissions that are contributing to violations of the lead NAAQS; (2) analyses of future year emissions reductions and air quality improvement resulting from already-adopted national, state, and local programs and from potential new state and local measures to meet the RACT, RACM, and RFP requirements in the area; (3) adopted emissions reduction measures with schedules for implementation and (4) contingency measures required under section 172(c)(9) of the CAA.

The requirements for the first two parts are described in the sections on emissions inventories and RACM/RACT, above and in the sections on air quality modeling and the attainment demonstration that follows immediately below. Requirements for the third and fourth parts are described in the sections on the control strategy and the contingency measures, respectively.

As stated in section V.C.2. above, the future case dispersion modeling is the attainment demonstration used to verify that the proposed control strategies will bring the area into attainment. In order to determine whether the planned emission reduction strategies will result in attainment of the NAAQS, the modeled maximum lead air concentration (based on a rolling three-month average) is added to the calculated background lead concentration of 0.020 μg/m^3, the predicted maximum three-month rolling average lead concentration is 0.148 μg/m^3. By comparison, the 2008 Lead NAAQS is 0.150 μg/m^3. Therefore, Missouri's modeling demonstrates attainment of the standard.

G. New Source Review (NSR)

Within the CAA, part D of title I requires SIP submittals to include a permit program for the construction and operation of new and modified major stationary sources. The current definition of nonattainment areas in Missouri, which for lead includes the Viburnum Trend area, is provided in Missouri rule 10 CSR 10–6.020. For installations in a nonattainment area, Missouri rule 10 CSR 10–6.060 requires a permit for construction of, or major modification to, an installation with potential to annually emit one hundred (100) tons or more of a nonattainment pollutant, or a permit for a modification at a major source with potential to annually emit one thousand two hundred (1,200) pounds of lead. Both rules have previously been approved by EPA as part of the SIP, as meeting the requirements of section 173 of the CAA, and EPA implementing rules at 40 CFR 51.165. (78 FR 19602; 78 FR 37457).

H. Contingency Measures

As required by CAA section 172(c)(9), the SIP submittal includes contingency measures to be implemented if EPA determines that the area has failed to make RFP or if the area fails to attain the NAAQS by December 2015. If the air quality data for any three-month rolling period after the implementation of the control measures identified in the 2013 Consent Judgment exceeds the 0.15 ug/m^3 three-month rolling average lead standard, BRRF shall implement the contingency measures set forth in the 2013 Consent Judgment. Missouri may also require implementation of contingency measures if Doe Run fails to implement the control strategy projects in accordance with the 2013 Consent Judgment.

The 2013 Consent Judgment contains the following contingency measures which apply to BRRF:

a. Ventilate the reverberatory feed storage building with a minimum design to achieve a negative pressure of 0.02 inches Hg within nine months' notice from Missouri.

b. Within a time frame to be determined by Missouri and BRRF, BRRF shall submit a work plan for a study to determine the best practices and best available control technology to achieve compliance with the 2008 Lead NAAQS. The study shall be completed and submitted to Missouri within 180 days from Missouri's approval of the

[6] *http://www.epa.gov/oar/lead/pdfs/2012ImplementationGuide.pdf.*

work plan. Within 60 days from receipt of the study, Missouri shall advise BRRF of whether the projects and timelines for implementation proposed by the study are acceptable. Upon Missouri's approval or 60 days with no comment, the projects identified by the study shall be implemented in accordance with the timeline therein and shall become a fully enforceable part of the 2013 Consent Judgment.

c. Pave inbound truck parking lot within 18 months of notice from Missouri of a 2008 Lead NAAQS violation.

d. Within a timeframe to be developed by Missouri and BRRF, BRRF shall submit and evaluation of the main baghouse capacity and will identify any projects that are deemed technically feasible and cost-effective to redistribute any excess capacity identified in the evaluation and for inclusion as contingency measures and provide an implementation timeframe. Within 60 days of receipt of the evaluation, Missouri will advise BRRF whether the projects and timelines are acceptable. Upon approval or after 60 days, the projects identified in the baghouse capacity study shall become an enforceable part of the 2013 Consent Judgment.

The contingency measures listed above shall be implemented upon notice from Missouri of a Lead NAAQS violation and shall be implemented in the order listed above for each subsequent Lead NAAQS violation should additional violations occur.

BRRF must notify Missouri within ten (10) days of completion of any contingency measure. Sixty days (60) after completion, BRRF will propose an additional qualified contingency measure to be added to the 2013 Consent Judgment, which will become part of the 2013 Consent Judgment and fully enforceable upon approval by Missouri. These additional contingency measures will also be subject to EPA approval as part of the SIP.

Doe Run or BRRF may also substitute new control(s) for the identified contingency measure(s) if Doe Run or BRRF identifies and demonstrates to Missouri and EPA's satisfaction that the alternative control measure(s) would achieve attainment with the 2008 lead NAAQS. The 2013 Consent Judgment also allows Doe Run or BRRF to change the order of implementation for contingency measures and time frames for completion upon approval by Missouri.

Changes to contingency measures would require a public hearing at the state level and EPA approval as a formal SIP revision. Until such time as EPA approves any substitute measure, the measures included in the approved SIP will be the enforceable measure. EPA does not intend to approve any substitutions that cannot be implemented in the same timeframe as the original measure. These measures will help ensure compliance with the 2008 lead NAAQS as well as meet the requirements of section 172(c)(9) of the CAA. EPA proposes to approve Missouri's SIP as meeting section 172(c)(9) of the CAA.

I. Enforceability

As specified in section 172(c)(6) and section 110(a)(2)(A) of the CAA, and 57 FR 13556, all measures and other elements in the SIP must be enforceable by the state and EPA. The enforceable document included in Missouri's SIP submittal is the 2013 Consent Judgment. The 2013 Consent Judgment contains all control and contingency measures with enforceable dates for implementation. The only exception relates to the Federally enforceable dates found in the 2011 Consent Decree. The 2013 Consent Judgment also includes monitoring, recordkeeping, and reporting requirements to ensure that the control and contingency measures are met. The state adopted the 2013 Consent Judgment into Missouri's state regulations on June 19, 2013, making it state-enforceable. Upon EPA approval of the SIP submission, the 2013 Consent Judgment will become state and Federally enforceable, and enforceable by citizens under section 304 of the CAA.

We note that the 2013 Consent Judgment also contains provisions for stipulated penalties should Doe Run or BRRF fail to comply with provisions of the 2013 Consent Judgment. The 2011 Consent Decree also contains stipulated penalty provisions. EPA is not bound by the state's 2013 Consent Judgment penalties. With regard to matters that are addressed by the 2011 Consent Decree, EPA may enforce against violations of this document under section 113 of the CAA or other Federal authorities, rather than the 2013 Consent Judgment, if EPA approves the 2013 Consent Judgment, as proposed in this action, into the SIP.

EPA proposes to approve Missouri's SIP as meeting sections 172(c)(6) and 110(a)(2)(A) of the CAA, and 57 FR 13556.

VI. Review of Revision to Missouri Rule Restricting Lead Emissions From Specific Lead Smelter-Refinery Installations

A. Background

Section 110 of the CAA requires states to develop air pollution regulations and control strategies to ensure that state air quality meets the NAAQS established by EPA. In order for the state regulations to be incorporated into the Federally-enforceable SIP, states must formally adopt the regulations and control strategies consistent with state and Federal requirements. States submit adopted rules and revisions to EPA for inclusion in the SIP. State rules and revisions approved by EPA under section 110 authority are incorporated into the Federally-approved and enforceable SIP.

As discussed above in paragraph I, Background, Missouri rule 10 CSR 10–6.120 ''Restriction of Emissions of Lead from Specific Lead Smelter—Refinery Installations'', establishes lead emissions limits from stacks at specific lead smelters including the Herculaneum facility in Herculaneum, Missouri, and BRRF in Boss, Missouri.

For enforceability, the Viburnum Trend area lead NAAQS attainment SIP relies upon the production limit imposed by Missouri rule 10 CSR 10–6.120, recordkeeping requirements, and test methods. The approval of the revision to the rule relies upon the modeling demonstration proposed in the lead NAAQS attainment SIP to demonstrate that the production limits will result in emissions limits that meet the standard. A technical analysis of the production limits proposed, reporting and recordkeeping requirements, and the test methods prescribed is conducted in the EPA Technical Support Document (TSD), which is included in the docket as materials relied upon for this proposed action. An abbreviated discussion of the information in the EPA TSD is discussed below.

B. Analysis of Production and Emissions Limits

As stated above, Missouri rule 10 CSR 10–6.120(B)(2) limits production at BRRF to 175,000 tons of Pb per year, and is consistent with the limit imposed by the Prevention of Significant Deterioration (PSD) permit issued to the facility. However, the Pb emissions from the present operations are significantly less than the previous operational configuration in the PSD permit. This is due to the elimination of the Rotary Melter, and the addition of control measures listed in Section 5.1 of the SIP

document, including two new baghouses, enclosure of the facility's process and materials handling areas under negative pressure to achieve the Secondary Lead NESHAP, and additional work practice standards also to comply with the NESHAP.

The Viburnum Trend area lead NAAQS attainment SIP and supporting Consent Judgment specify Stack Emission Limits required to attain the 2008 Pb NAAQS (see table 4, Stack Emission Limits). Although Missouri rule 10 CSR 10–6.120 establishes the maximum Pb production limit for BRRF rather than a specific emission limitation by stack, the Pb production limit, or throughput, correlates with the stack emission limits modeled in the SIP. The emissions limits by source are detailed in appendix H of the attainment demonstration SIP.

The modeled total emissions in the attainment demonstration SIP are 176,482 tons of Pb produced per year. Thus, the ''Future'' case modeling demonstrates that under conservative production rates (*i.e.,* slightly higher than the maximum allowable by the revised Missouri rule), the facility still attains the 2008 Pb NAAQS.

As discussed in paragraph V.C. above, EPA has conducted an independent analysis of Missouri's attainment SIP modeling and has determined that the control measures will result in attainment of the 2008 lead NAAQS. The detailed analysis, contained in EPA's TSD, of the Pb production limits for BRRF imposed by Missouri rule 10 CSR 10–6.120 demonstrates that they correspond with the SIP control measures, expressed as stack emission limits, imposed by the Viburnum Trend area lead NAAQS attainment SIP and supporting Consent Judgment and will provide for attainment of the 2008 Pb NAAQS. As demonstrated above, the revision to the Missouri SIP does not interfere with attainment and reasonable further progress.

Pursuant to the March 4, 2015, withdrawal request from Missouri, EPA is not taking action on Missouri rule 10 CSR 10–6.120, General Provision (3)(B)1, which limits main stack, number 7 and 9 baghouse stack and number 8 baghouse stack lead emissions at the Doe Run primary lead smelter-refinery in Herculaneum, Missouri.[7] In addition, EPA is not taking action on Missouri rule 10 CSR 10–6.120, General Provision (3)(B)2., which limits main stack lead emissions at BRRF to 0.00087 grains per dry standard cubic feet (gr/dscf) of air. Missouri has withdrawn its request for approval of these limits into the SIP because they no longer represent operating conditions at the facility and are higher than the secondary lead NESHAP, respectively.

C. Work Practice Manual (WPM)

Missouri rule 10 CSR 10–6.120(3)(C) contains the requirements for both the Herculaneum facility and BRRF to control fugitive emissions of lead from all process and area sources by work practices. The work practices are required to be submitted to the state in the form of a WPM for the state director's review and approval.

Any change to the WPM requires state director approval and the change shall not lessen the effectiveness of the fugitive emission reductions for the work practice involved. Written approval by the director is required before any change becomes effective.

If the director determines that a change in the WPM is warranted, the state director shall notify the facility in writing. The facility must make the required change(s) within 30 days of written notice from the state director.

The requirements for the WPM are consistent with the modeled controls of fugitive emissions in the Viburnum Trend area attainment SIP. The SIP relies on the Missouri rule for implementation of work practices contained in the approved manual. Therefore, EPA proposes to approve this portion of Missouri rule 10 CSR 10–6.120.

D. Reporting and Record Keeping

Missouri rule 10 CSR 10–6.120(4) contains the requirement for the Herculaneum facility and BRRF to keep records and files generated by the WPM's implementation. The required records include records of inspections conducted of fugitive emissions control equipment such as hoods, air ducts and exhaust fans, and records that demonstrate compliance with the sampling methods required for stack testing discussed below. These records are required to be maintained at the facility for a minimum of two (2) years and shall be made available to the state director upon request.

The requirements for the reporting and record keeping are necessary to determine that the facility is operating in accordance with the modeled controls of fugitive emissions in the Viburnum Trend area attainment SIP. The SIP relies on the Missouri rule for implementation of work practices contained in the approved manual which are documented by the reporting and record keeping requirements contained therein. Therefore, EPA proposes to approve this portion of Missouri rule 10 CSR 10–6.120.

E. Test Methods

Missouri rule 10 CSR 10–6.120(5) contains the required test methods for stack testing in accordance with the requirements for visible emissions contained in Missouri rule 10 CSR 10–6.030(9), for quantifying Pb in stack gases in accordance with Missouri rule 10 CSR 10–6.030(12), and for measuring Pb in ambient air in accordance with Missouri rule 10 CSR 10–030(12). These methods have all been determined to comply with the equivalent EPA Methods 12 and 29 promulgated by 40 CFR part 60 appendix A.

The Test Methods required by the revised Missouri rule are necessary to determine that the facility is complying with the stack emission limits imposed by the Viburnum Trend Area attainment SIP. The SIP relies on the Missouri rule for the Test Methods and reporting of the results of testing to determine compliance. Therefore, EPA proposes to approve this portion of Missouri rule 10 CSR 10–6.120.

VII. Proposed Action

EPA is proposing to grant full approval of Missouri's attainment demonstration SIP for the Viburnum Trend 2008 lead NAAQS nonattainment area. EPA believes that the SIP submitted by Missouri satisfies the applicable requirements of the CAA identified in EPA's Final Rule (73 FR 66964, October 15, 2008), and will result in attainment of the 0.15 ug/m^3 standard in the Viburnum Trend, Missouri, area.

Pursuant to Missouri's March 4, 2015, withdrawal request, EPA is not taking action on the Doe Run primary lead smelter-refinery emissions limits in 10 CSR 10–6.120(3)(B)1. and table I, and the 0.00087 gr/dscf main stack emissions limit for BRRF in 10 CSR 10–6.120(3)(B)2. EPA proposes to approve the remaining portions of the revision to Missouri rule 10 CSR 10–6.120 as part of Missouri's SIP.

Statutory and Executive Order Reviews

In this action, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference Missouri Rule 10 CSR 10–6.120 (with the exclusions of Paragraph 10–6.120 (3)(B)1. and Table 1, and the 0.00087 gr/dscf main stack emissions limit for

[7] Missouri's State Implementation Plan for the Jefferson County Lead Nonattainment Area and associated lead emissions limits for ongoing refinery operations at the Doe Run Refinery in Herculaneum, Missouri were approved by EPA on October 20, 2014. 79 FR 62574.

BRRF) described in the proposed amendments to 40 CFR part 52 set forth below. EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011). This action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rulemaking will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rulemaking would approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it 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).

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

This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). Thus Executive Order 13132 does not apply to this action. This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the CAA. This rulemaking also is not subject to Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) because it approves a state rule implementing a Federal standard.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a state submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA when it reviews a state submission, to use VCS in place of a state submission that otherwise satisfies the provisions of the CAA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Burden is defined at 5 CFR 1320.3(b).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this proposed rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**.

A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 31, 2015. Filing a petition for reconsideration by the Administrator of this proposed rule does not affect the finality of this rulemaking 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 future rule or action.

List of Subjects in 40 CFR Part 52

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

Dated: May 19, 2015.

Mark Hague,

Acting Regional Administrator, Region 7.

For the reasons stated in the preamble, the EPA proposes to amend 40 CFR part 52 as set forth below:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart AA—Missouri

■ 2. In § 52. 1320 amend the table in paragraph (c) by revising the entry for Missouri Rule 10 CSR 10–6.120 and the table in paragraph (d) by adding new entry (29) to read as follows:

§ 52.1320 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED MISSOURI REGULATIONS

Missouri citation	Title	State effective date	EPA approval date	Explanation
Missouri Department of Natural Resources				
*	*	*	*	*
Chapter 6—Air Quality Standards, Definitions, Sampling and Reference Methods, and Air Pollution Control Regulations for the State of Missouri				
*	*	*	*	*
10–6.120	Restriction of Emissions of Lead from Specific Lead Smelter-Refinery Installations.	3/30/09	6/1/15 *and [Insert* ***Federal Register*** *citation].*	Paragraph (3)(B)1 and Table, Provision Pertaining to Limitations of Lead Emissions from Specific Installations, is not approved as part of the SIP. The requirement to limit main stack lead emissions at BRRF to 0.00087 gr/dscf lead in Paragraph (3)(B)2 is not approved as part of the SIP.
*	*	*	*	*

* * * * * (d) * * *

EPA-APPROVED MISSOURI SOURCE-SPECIFIC PERMITS AND ORDERS

Name of source	Order/permit number	State effective date	EPA approval date	Explanation
*	*	*	*	*
(29) Doe Run Buick Resource Recycling Facility.	Consent Judgment 13IR–CC00016	7/29/13	6/1/15 *and [Insert* ***Federal Register*** *citation]*	

* * * * *

[FR Doc. 2015–13128 Filed 5–29–15; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2012–0972, FRL–9928–52–Region 8]

Promulgation of State Implementation Plan Revisions; Infrastructure Requirements for the 2008 Ozone, 2008 Lead, and 2010 NO2 National Ambient Air Quality Standards; Colorado

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve elements of State Implementation Plan (SIP) revisions from the State of Colorado to demonstrate the State meets infrastructure requirements of the Clean Air Act (Act, CAA) for the National Ambient Air Quality Standards (NAAQS) promulgated for ozone on March 12, 2008; lead (Pb) on October 15, 2008; and nitrogen dioxide (NO_2) on January 22, 2010. Section 110(a) of the CAA requires that each state submit a SIP for the implementation, maintenance, and enforcement of each NAAQS promulgated by EPA.

DATES: Written comments must be received on or before July 1, 2015.

ADDRESSES: The EPA has established a docket for this action under Docket Identification Number EPA–R08–OAR–2012–0972. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in the hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at EPA Region 8, Office of Partnership and Regulatory Assistance, Air Program, 1595 Wynkoop Street, Denver, Colorado, 80202–1129. The EPA requests that you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. The Regional Office's official hours of business are Monday through Friday, 8:00 a.m.–4:00 p.m., excluding federal holidays. An electronic copy of the State's SIP compilation is also available at *http://www.epa.gov/region8/air/sip.html.*

FOR FURTHER INFORMATION CONTACT: Abby Fulton, Air Program, U.S. Environmental Protection Agency (EPA), Region 8, Mail Code 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129, 303–312–6563, *fulton.abby@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

What should I consider as I prepare my comments for EPA?

1. *Submitting Confidential Business Information (CBI).* Do not submit CBI to EPA through *http://www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD–ROM that you mail to EPA, mark

the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** volume, date, and page number);
- Follow directions and organize your comments;
- Explain why you agree or disagree;
- Suggest alternatives and substitute language for your requested changes;
- Describe any assumptions and provide any technical information and/or data that you used;
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced;
- Provide specific examples to illustrate your concerns, and suggest alternatives;
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats; and,
- Make sure to submit your comments by the comment period deadline identified.

II. Background

On March 12, 2008, EPA promulgated a new NAAQS for ozone, revising the levels of the primary and secondary 8-hour ozone standards from 0.08 parts per million (ppm) to 0.075 ppm (73 FR 16436). Subsequently, on October 15, 2008, EPA revised the level of the primary and secondary Pb NAAQS from 1.5 micrograms per cubic meter ($\mu g/m^3$) to 0.15 $\mu g/m^3$ (73 FR 66964). On January 22, 2010, EPA promulgated a new 1-hour primary NAAQS for NO_2 at a level of 100 parts per billion (ppb) while retaining the annual standard of 53 ppb. The 2010 NO_2 NAAQS is expressed as the three year average of the 98th percentile of the annual distribution of daily maximum 1-hour average concentrations. The secondary NO_2 NAAQS remains unchanged at 53 ppb (75 FR 6474, Feb. 9, 2010).

Under sections 110(a)(1) and (2) of the CAA, states are required to submit infrastructure SIPs to ensure their SIPs provide for implementation, maintenance, and enforcement of the NAAQS. These submissions must contain any revisions needed for meeting the applicable SIP requirements of section 110(a)(2), or certifications that their existing SIPs for ozone, Pb, and NO_2 already meet those requirements. EPA highlighted this statutory requirement in an October 2, 2007, guidance document entitled ''Guidance on SIP Elements Required Under Sections 110(a)(1) and (2) for the 1997 8-hour Ozone and $PM_{2.5}$ National Ambient Air Quality Standards'' (2007 Memo). On September 25, 2009, EPA issued an additional guidance document pertaining to the 2006 fine particulate matter ($PM_{2.5}$) NAAQS entitled ''Guidance on SIP Elements Required Under Sections 110(a)(1) and (2) for the 2006 24-Hour Fine Particle ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS)'' (2009 Memo), followed by the October 14, 2011, ''Guidance on Infrastructure SIP Elements Required Under Sections 110(a)(1) and (2) for the 2008 Lead (Pb) National Ambient Air Quality Standards (NAAQS)'' (2011 Memo). Most recently, EPA issued ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and (2)'' on September 13, 2013 (2013 Memo).

III. What is the scope of this rulemaking?

EPA is acting upon the SIP submissions from Colorado that address the infrastructure requirements of CAA sections 110(a)(1) and 110(a)(2) for the 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS. The requirement for states to make a SIP submission of this type arises out of CAA section 110(a)(1). Pursuant to section 110(a)(1), states must make SIP submissions ''within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof),'' and these SIP submissions are to provide for the ''implementation, maintenance, and enforcement'' of such NAAQS. The statute directly imposes on states the duty to make these SIP submissions, and the requirement to make the submissions is not conditioned upon EPA taking any action other than promulgating a new or revised NAAQS. Section 110(a)(2) includes a list of specific elements that ''[e]ach such plan'' submission must address.

EPA has historically referred to these SIP submissions made for the purpose of satisfying the requirements of CAA sections 110(a)(1) and 110(a)(2) as ''infrastructure SIP'' submissions. Although the term ''infrastructure SIP'' does not appear in the CAA, EPA uses the term to distinguish this particular type of SIP submission from submissions that are intended to satisfy other SIP requirements under the CAA, such as ''nonattainment SIP'' or ''attainment plan SIP'' submissions to address the nonattainment planning requirements of part D of title I of the CAA; ''regional haze SIP'' submissions required by EPA rule to address the visibility protection requirements of CAA section 169A; and nonattainment new source review (NSR) permit program submissions to address the permit requirements of CAA, title I, part D.

Section 110(a)(1) addresses the timing and general requirements for infrastructure SIP submissions, and section 110(a)(2) provides more details concerning the required contents of these submissions. The list of required elements provided in section 110(a)(2) contains a wide variety of disparate provisions, some of which pertain to required legal authority, some of which pertain to required substantive program provisions, and some of which pertain to requirements for both authority and substantive program provisions.[1] EPA therefore believes that while the timing requirement in section 110(a)(1) is unambiguous, some of the other statutory provisions are ambiguous. In particular, EPA believes that the list of required elements for infrastructure SIP submissions provided in section 110(a)(2) contains ambiguities concerning what is required for inclusion in an infrastructure SIP submission.

Examples of some of these ambiguities and the context in which EPA interprets the ambiguous portions of section 110(a)(1) and 110(a)(2) are discussed at length in our notice of proposed rulemaking: Promulgation of State Implementation Plan Revisions; Infrastructure Requirements for the 1997 and 2006 $PM_{2.5}$ 2008 Lead, 2008 Ozone, and 2010 NO_2 National Ambient Air Quality Standards; South Dakota (79 FR 71040 Dec. 1, 2014) under ''III. What is the Scope of this Rulemaking?''

With respect to certain other issues, EPA does not believe that an action on a state's infrastructure SIP submission is necessarily the appropriate type of

[1] For example: Section 110(a)(2)(E)(i) provides that states must provide assurances that they have adequate legal authority under state and local law to carry out the SIP; section 110(a)(2)(C) provides that states must have a SIP-approved program to address certain sources as required by part C of title I of the CAA; and section 110(a)(2)(G) provides that states must have legal authority to address emergencies as well as contingency plans that are triggered in the event of such emergencies.

action in which to address possible deficiencies in a state's existing SIP. These issues include: (i) Existing provisions related to excess emissions from sources during periods of startup, shutdown, or malfunction (SSM) that may be contrary to the CAA and EPA's policies addressing such excess emissions; (ii) existing provisions related to ''director's variance'' or ''director's discretion'' that may be contrary to the CAA because they purport to allow revisions to SIP-approved emissions limits while limiting public process or not requiring further approval by EPA; and (iii) existing provisions for Prevention of Significant Deterioration (PSD) programs that may be inconsistent with current requirements of EPA's ''Final NSR Improvement Rule,'' 67 FR 80186, Dec. 31, 2002, as amended by 72 FR 32526, June 13, 2007. (''NSR Reform'').

IV. What infrastructure elements are required under Sections 110(a)(1) and (2)?

CAA section 110(a)(1) provides the procedural and timing requirements for SIP submissions after a new or revised NAAQS is promulgated. Section 110(a)(2) lists specific elements the SIP must contain or satisfy. These infrastructure elements include requirements such as modeling, monitoring, and emissions inventories, which are designed to assure attainment and maintenance of the NAAQS. The elements that are the subject of this action are listed below.

- 110(a)(2)(A): Emission limits and other control measures.
- 110(a)(2)(B): Ambient air quality monitoring/data system.
- 110(a)(2)(C): Program for enforcement of control measures.
- 110(a)(2)(D): Interstate transport.
- 110(a)(2)(E): Adequate resources and authority, conflict of interest, and oversight of local governments and regional agencies.
- 110(a)(2)(F): Stationary source monitoring and reporting.
- 110(a)(2)(G): Emergency powers.
- 110(a)(2)(H): Future SIP revisions.
- 110(a)(2)(J): Consultation with government officials; public notification; and PSD and visibility protection.
- 110(a)(2)(K): Air quality modeling/data.
- 110(a)(2)(L): Permitting fees.
- 110(a)(2)(M): Consultation/participation by affected local entities.

A detailed discussion of each of these elements is contained in the next section.

Two elements identified in section 110(a)(2) are not governed by the three year submission deadline of section 110(a)(1) and are therefore not addressed in this action. These elements relate to part D of Title I of the CAA, and submissions to satisfy them are not due within three years after promulgation of a new or revised NAAQS, but rather are due at the same time nonattainment area plan requirements are due under section 172. The two elements are: (1) Section 110(a)(2)(C) to the extent it refers to permit programs (known as ''nonattainment NSR'') required under part D, and (2) section 110(a)(2)(I), pertaining to the nonattainment planning requirements of part D. As a result, this action does not address infrastructure elements related to the nonattainment NSR portion of section 110(a)(2)(C) or related to 110(a)(2)(I). Furthermore, EPA interprets the CAA section 110(a)(2)(J) provision on visibility as not being triggered by a new NAAQS because the visibility requirements in part C, title 1 of the CAA are not changed by a new NAAQS.

V. How did Colorado address the infrastructure elements of Sections 110(a)(1) and (2)?

The Colorado Department of Public Health and Environment (CDPHE) submitted certifications of Colorado's infrastructure SIP for the 2008 Pb NAAQS on July 26, 2012; the 2008 ozone NAAQS on December 31, 2012; and the 2010 NO_2 NAAQS on March 7, 2013. Colorado's infrastructure certifications demonstrate how the State, where applicable, has plans in place that meet the requirements of section 110 for the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS. These plans reference the current Air Quality Control Commission (AQCC) regulations and Colorado Revised Statutes (C.R.S.). These submittals are available within the electronic docket for today's proposed action at *www.regulations.gov.* The AQCC regulations referenced in the submittals are publicly available at *https://www.colorado.gov/pacific/cdphe/aqcc-regs* and *http://www.lexisnexis.com/hottopics/colorado/.* Colorado's SIP, air pollution control regulations, and statutes that have been previously approved by EPA and incorporated into the Colorado SIP can be found at 40 CFR 52.320.

VI. Analysis of the State Submittals

1. Emission limits and other control measures: Section 110(a)(2)(A) requires SIPs to include enforceable emission limitations and other control measures, means, or techniques (including economic incentives such as fees, marketable permits, and auctions of emissions rights), as well as schedules and timetables for compliance as may be necessary or appropriate to meet the applicable requirements of this Act.

Multiple SIP-approved AQCC regulations citied in Colorado's certifications provide enforceable emission limitations and other control measures, means or techniques, schedules for compliance, and other related matters necessary to meet the requirements of the CAA section 110(a)(2)(A) for the 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS, subject to the following clarifications.

First, EPA does not consider SIP requirements triggered by the nonattainment area mandates in part D of Title I of the CAA to be governed by the submission deadline of section 110(a)(1). Nevertheless, Colorado has included some SIP provisions originally submitted in response to part D requirements in its certification for the infrastructure requirements of section 110(a)(2). For the purposes of this action, EPA is reviewing any rules originally submitted in response to part D requirements solely for the purposes of determining whether they support a finding that the State has met the basic infrastructure requirements of section 110(a)(2). For example, in response to the requirement to have enforceable emission limitations under section 110(a)(2)(A), Colorado cited to rules in Regulation Number 7 that were submitted to meet the reasonably available control technology (RACT) requirements of part D. EPA is here approving those rules as meeting the requirement to have enforceable emission limitations on ozone precursors; any judgment about whether those emission limitations discharge the State's obligation to impose RACT under part D will be made separately, in an action reviewing those rules pursuant to the requirements of part D. Colorado also referenced SIP provisions that are relevant, such as limits on emissions of particulate matter (PM) in Regulation 1, woodburning controls in Regulation 4, and the State's minor NSR and PSD programs in Regulation 3. We propose to find these provisions adequately address the requirements of element (A), again subject to the clarifications made in this notice.

Second, in this action, EPA is not proposing to approve or disapprove any existing state rules with regard to director's discretion or variance provisions. A number of states have such provisions which are contrary to the CAA and existing EPA guidance (52 FR 45109, Nov. 24, 1987), and the Agency plans to take action in the future to address such state regulations. In the meantime, EPA encourages any state

having a director's discretion or variance provision which is contrary to the CAA and EPA guidance to take steps to correct the deficiency as soon as possible.

Third and finally, in this action, EPA is also not proposing to approve or disapprove any existing state provision with regard to excess emissions during SSM or operations at a facility. A number of states have SSM provisions which are contrary to the CAA and existing EPA guidance [2] and the Agency is addressing such state regulations separately (78 FR 12460, Feb. 22, 2013).

2. Ambient air quality monitoring/data system: Section 110(a)(2)(B) requires SIPs to provide for establishment and operation of appropriate devices, methods, systems, and procedures necessary to ''(i) monitor, compile, and analyze data on ambient air quality, and (ii) upon request, make such data available to the Administrator.''

The Colorado Air Pollution Control Division (APCD) periodically submits a Quality Management Plan and a Quality Assurance Project Plan to EPA Region 8. These plans cover procedures to monitor and analyze data. The provisions for episode monitoring, data compilation and reporting, public availability of information, and annual network reviews are found in the statewide monitoring SIP (58 FR 49435, Sept. 23, 1993). As part of the monitoring SIP, Colorado submits an Annual Monitoring Network Plan (AMNP) each year for EPA approval. EPA approved 2013 and 2014 network changes through an AMNP response letter (contained within the docket) mailed to CDPHE on March 13, 2015.

In the AMNP response letter, EPA noted a deficiency in Colorado's AMNP regarding NO_2 monitoring. 40 CFR 58.10(a)(5)(iv) requires that ''a plan for establishing a second near-road NO_2 monitor in any [Core Based Statistical Area] [CBSA] with a population of 2,500,000 or more persons, or a second monitor in any CBSA with a population of 500,000 or more persons that has one or more roadway segments with 250,000 or greater [annual average daily traffic] counts, in accordance with the requirements of Appendix D, section 4.3.2 to this part, shall be submitted as part of the Annual Monitoring Network Plan to the EPA Regional Administrator by July 1, 2014. The plan shall provide for these required monitors to be operational by January 1, 2015.'' Colorado was required to start its second near-road NO_2 monitor by January 1, 2015. The State did not meet this deadline. However, in a letter dated March 31, 2015 (contained within the docket) CDPHE committed to install and operate the second near-road NO_2 monitoring site by December 31, 2015 at I–25/Acoma Street and 49th Avenue in Denver. The State will notify EPA once the monitor is operational, which will then satisfy the requirements of 40 CFR 58.10(a)(5)(iv).

We find that Colorado's SIP and practices are adequate for the ambient air quality monitoring and data system requirements for the 2008 ozone and 2010 Pb NAAQS; and therefore, propose to approve the infrastructure SIP for the 2008 ozone and 2008 Pb NAAQS for this element.

CAA 110(k)(4) states ''The Administrator may approve a plan revision based on a commitment of the State to adopt specific enforceable measures by a date certain, but not later than 1 year after the date of approval of the plan revision. Any such conditional approval shall be treated as a disapproval if the State fails to comply with such commitment.'' Based on Colorado's commitment to install and operate the second near-road NO_2 monitoring site no later than December 31, 2015, we propose to conditionally approve this element for the 2010 NO_2 NAAQS. If however, the State fails to meet the deadline for installing and operating the near-road NO_2 monitor, EPA's conditional approval, if finalized, will revert automatically to a disapproval.

3. Program for enforcement of control measures: Section 110(a)(2)(C) requires SIPs to include a program to provide for the enforcement of the measures described in subparagraph (A), and regulation of the modification and construction of any stationary source within the areas covered by the plan as necessary to assure NAAQS are achieved, including a permit program as required in parts C and D.

To generally meet the requirements of section 110(a)(2)(C), the State is required to have SIP-approved PSD, nonattainment NSR, and minor NSR permitting programs adequate to implement the 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS. As explained elsewhere in this action, EPA is not evaluating nonattainment related provisions, such as the nonattainment NSR program required by part D of the Act. EPA is evaluating the State's PSD program as required by part C of the Act, and the State's minor NSR program as required by 110(a)(2)(C).

PSD Requirements

With respect to elements (C) and (J), EPA interprets the CAA to require each state to make an infrastructure SIP submission for a new or revised NAAQS that demonstrates that the air agency has a complete PSD permitting program meeting the current requirements for all regulated NSR pollutants. The requirements of element (D)(i)(II) may also be satisfied by demonstrating the air agency has a complete PSD permitting program correctly addressing all regulated NSR pollutants. Colorado has shown that it currently has a PSD program in place that covers all regulated NSR pollutants, including greenhouse gases (GHGs).

EPA's ''Final Rule to Implement the 8-Hour Ozone National Ambient Air Quality Standard—Phase 2; Final Rule to Implement Certain Aspects of the 1990 Amendments Relating to New Source Review and Prevention of Significant Deterioration as They Apply in Carbon Monoxide, Particulate Matter, and Ozone NAAQS; Final Rule for Reformulated Gasoline'' (Phase 2 Rule) was published on November 29, 2005 (70 FR 71612). Among other requirements, the Phase 2 Rule obligated states to revise their PSD programs to explicitly identify NO_X as a precursor to ozone. EPA approved revisions to Colorado's PSD program reflecting these requirements on January 9, 2012 (77 FR 1027), and therefore, Colorado has met the infrastructure SIP requirements of section 110(a)(2)(C) with respect to 2008 ozone.

On June 23, 2014, the United States Supreme Court issued a decision addressing the application of PSD permitting requirements to GHG emissions, *Utility Air Regulatory Group* v. *Environmental Protection Agency,* 134 S.Ct. 2427. The Supreme Court said that EPA may not treat GHGs as an air pollutant for purposes of determining whether a source is a major source required to obtain a PSD permit. The Supreme Court also said that EPA could continue to require that PSD permits, otherwise required based on emissions of pollutants other than GHGs, contain limitations on GHG emissions based on the application of Best Available Control Technology (BACT). In order to act consistently with its interpretation of the Court's decision pending further judicial action to effectuate the decision, EPA is not continuing to apply EPA regulations that would require that SIPs include permitting requirements that the Supreme Court found impermissible. Specifically, EPA is not

[2] Steven Herman, Assistant Administrator for Enforcement and Compliance Assurance, and Robert Perciasepe, Assistant Administrator for Air and Radiation, Memorandum to EPA Air Division Directors, ''State Implementation Plans (SIPs): Policy Regarding Emissions During Malfunctions, Startup, and Shutdown.'' (Sept. 20, 1999).

applying the requirement that a state's SIP-approved PSD program require that sources obtain PSD permits when GHGs are the only pollutant (i) that the source emits or has the potential to emit above the major source thresholds, or (ii) for which there is a significant emissions increase and a significant net emissions increase from a modification (*e.g.,* 40 CFR 51.166(b)(48)(v)). EPA anticipates a need to revise federal PSD rules in light of the Supreme Court opinion. In addition, EPA anticipates that many states will revise their existing SIP-approved PSD programs in light of the Supreme Court's decision in Utility Air. The timing and content of subsequent EPA actions with respect to EPA regulations and state PSD program approvals are expected to be informed by additional legal process before the United States Court of Appeals for the District of Columbia Circuit. At this juncture, EPA is not expecting states to have revised their PSD programs for purposes of infrastructure SIP submissions and is only evaluating such submissions to assure that the state's program correctly addresses GHGs consistent with the Supreme Court's decision.

At present, EPA has determined that Colorado's SIP is sufficient to satisfy elements (C), (D)(i)(II), and (J) with respect to GHGs because the PSD permitting program previously approved by EPA [3] into the SIP continues to require that PSD permits (otherwise required based on emissions of pollutants other than GHGs) contain limitations on GHG emissions based on the application of BACT. Although the approved Colorado PSD permitting program may currently contain provisions that are no longer necessary in light of the Utility Air decision, this does not render the infrastructure SIP submission inadequate to satisfy elements (C), (D)(i)(II), and (J). The SIP contains the necessary PSD requirements at this time, and the application of those requirements is not impeded by the presence of other previously-approved provisions regarding the permitting of sources of GHGs that EPA does not consider necessary at this time in light of the Supreme Court decision. Accordingly, the Utility Air decision does not affect EPA's proposed approval of Colorado's infrastructure SIP as to the requirements of elements (C), (D)(i)(II), and (J).

Finally, we evaluate the PSD program with respect to current requirements for $PM_{2.5}$. In particular, on May 16, 2008, EPA promulgated the rule, ''Implementation of the New Source Review Program for Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$)'' (73 FR 28321) and on October 20, 2010 EPA promulgated the rule, ''Prevention of Significant Deterioration (PSD) for Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$)—Increments, Significant Impact Levels (SILs) and Significant Monitoring Concentration (SMC)'' (75 FR 64864). EPA regards adoption of these $PM_{2.5}$ rules as a necessary requirement when assessing a PSD program for the purposes of element (C).

On January 4, 2013, the U.S. Court of Appeals, in *Natural Resources Defense Council* v. *EPA,* 706 F.3d 428 (D.C. Cir.), issued a judgment that remanded EPA's 2007 and 2008 rules implementing the 1997 $PM_{2.5}$ NAAQS. The court ordered EPA to ''repromulgate these rules pursuant to Subpart 4 consistent with this opinion.'' *Id.* at 437. Subpart 4 of part D, Title 1 of the CAA establishes additional provisions for PM nonattainment areas.

The 2008 implementation rule addressed by the court decision, ''Implementation of New Source Review (NSR) Program for Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$),'' (73 FR 28321, May 16, 2008), promulgated NSR requirements for implementation of $PM_{2.5}$ in nonattainment areas (nonattainment NSR) and attainment/unclassifiable areas (PSD). As the requirements of Subpart 4 only pertain to nonattainment areas, EPA does not consider the portions of the 2008 Implementation rule that address requirements for $PM_{2.5}$ attainment and unclassifiable areas to be affected by the court's opinion. Moreover, EPA does not anticipate the need to revise any PSD requirements promulgated in the 2008 Implementation rule in order to comply with the court's decision. Accordingly, EPA's proposed approval of Colorado's infrastructure SIP as to elements C or J with respect to the PSD requirements promulgated by the 2008 Implementation rule does not conflict with the court's opinion.

The court's decision with respect to the nonattainment NSR requirements promulgated by the 2008 Implementation rule also does not affect EPA's action on the present infrastructure action. EPA interprets the Act to exclude nonattainment area requirements, including requirements associated with a nonattainment NSR program, from infrastructure SIP submissions due three years after adoption or revision of a NAAQS. Instead, these elements are typically referred to as nonattainment SIP or attainment plan elements, which would be due by the dates statutorily prescribed under subpart 2 through 5 under part D, extending as far as 10 years following designations for some elements.

The second PSD requirement for $PM_{2.5}$ is contained in EPA's October 20, 2010 rule, ''Prevention of Significant Deterioration (PSD) for Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$)—Increments, Significant Impact Levels (SILs) and Significant Monitoring Concentration (SMC)'' (75 FR 64864). EPA regards adoption of the $PM_{2.5}$ increments as a necessary requirement when assessing a PSD program for the purposes of element (C).

On May 11, 2012, the State submitted revisions to Regulation 3 that adopted all elements of the 2008 Implementation Rule and the 2010 $PM_{2.5}$ Increment Rule. However, the submittal contained a definition of Major Source Baseline Date which was inconsistent with 40 CFR 51.166(b)(14)(i). On May 13, 2013, the State submitted revisions to Regulation 3 which incorporate the definition of Major Source Baseline Date which was consistent with 40 CFR 51.166(b)(14)(i). These submitted revisions make Colorado's PSD program up to date with respect to current requirements for $PM_{2.5}$. EPA approved the necessary portions of Colorado's May 11, 2012 and May 13, 2013 submissions which incorporate the requirements of the 2008 $PM_{2.5}$ Implementation Rule and the 2010 $PM_{2.5}$ Increment Rule on September 23, 2013 (78 FR 58186). Colorado's SIP-approved PSD program meets current requirements for $PM_{2.5}$. EPA therefore is proposing to approve Colorado's SIP for the 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS with respect to the requirement in section 110(a)(2)(C) to include a permit program in the SIP as required by part C of the Act.

Minor NSR

The State has a SIP-approved minor NSR program, adopted under section 110(a)(2)(C) of the Act. The minor NSR program is found in Regulation 3 of the Colorado SIP, and was originally approved by EPA as Regulation 3 of the SIP (*see* 68 FR 37744, June 25, 2003). Since approval of the minor NSR program, the State and EPA have relied on the program to assure that new and modified sources not captured by the major NSR permitting programs do not interfere with attainment and maintenance of the NAAQS.

EPA is proposing to approve Colorado's infrastructure SIP for the 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS with respect to the general

[3] EPA's proposed notice at 78 FR 30830 (May 23, 2013) includes a discussion of the history of Colorado's PSD program approvals for GHGs.

requirement in section 110(a)(2)(C) to include a program in the SIP that regulates the modification and construction of any stationary source as necessary to assure that the NAAQS are achieved.

4. Interstate Transport: The interstate transport provisions in CAA section 110(a)(2)(D)(i) (also called ''good neighbor'' provisions) require each state to submit a SIP that prohibits emissions that will have certain adverse air quality effects in other states. CAA section 110(a)(2)(D)(i) identifies four distinct elements related to the impacts of air pollutants transported across state lines. The two elements under section 110(a)(2)(D)(i)(I) require SIPs to contain adequate provisions to prohibit any source or other type of emissions activity within the state from emitting air pollutants that will (element 1) contribute significantly to nonattainment in any other state with respect to any such national primary or secondary NAAQS, and (element 2) interfere with maintenance by any other state with respect to the same NAAQS. The two elements under section 110(a)(2)(D)(i)(II) require SIPs to contain adequate provisions to prohibit emissions that will interfere with measures required to be included in the applicable implementation plan for any other state under part C (element 3) to prevent significant deterioration of air quality or (element 4) to protect visibility. In this action, EPA is addressing all four elements of CAA section 110(a)(2)(D)(i).

In this action, EPA is addressing the 2008 Pb and 2010 NO_2 NAAQS with regard to elements 1 (significant contribution to nonattainment) and 2 (interference with maintenance). EPA is addressing elements 3 (interference with PSD) and 4 (interference with visibility protection) of 110(a)(2)(D)(i) with regard to the 2008 Ozone, 2008 Pb and 2010 NO_2 NAAQS. We are not addressing elements 1 and 2 for the 2008 ozone NAAQS in this action. These elements will be addressed in a later rulemaking.

A. Evaluation of Significant Contribution to Nonattainment and Interference With Maintenance

2008 Pb NAAQS

Colorado's analysis of potential interstate transport for the 2008 Pb NAAQS includes considerations of Colorado's Pb emissions inventory, and the distance of Pb sources in Colorado to nearby states. The State's analysis is available in the docket for this action.

As noted in the 2011 Memo, there is a sharp decrease in Pb concentrations, at least in the coarse fraction, as the distance from a Pb source increases. For this reason, EPA found that the ''requirements of subsection (2)(D)(i)(I) (elements 1 and 2) could be satisfied through a state's assessment as to whether or not emissions from Pb sources located in close proximity to their state borders have emissions that impact the neighboring state such that they contribute significantly to nonattainment or interfere with maintenance in that state.'' [4] In that guidance document, EPA further specified that any source appeared unlikely to contribute significantly to nonattainment unless it was located less than 2 miles from a state border and emitted at least 0.5 tons per year of Pb. Colorado's 110(a)(2)(D)(i)(I) analysis specifically noted that there are no sources in the State that meet both of these criteria. EPA concurs with the State's analysis and conclusion that no Colorado sources have the combination of Pb emission levels and proximity to neighboring states to contribute significantly to nonattainment in or interfere with maintenance by other states for this NAAQS. Colorado's SIP is therefore adequate to ensure that such impacts do not occur. We are proposing to approve Colorado's submission in that its SIP meets the requirements of section 110(a)(2)(D)(i) for the 2008 Pb NAAQS.

2010 NO_2 NAAQS

Colorado's 2010 NO_2 submission notes that all states are currently designated by EPA as unclassifiable/attainment for NO_2, and determines that it is therefore unlikely that Colorado contributes to nonattainment or interferes with maintenance for NO_2 in any other state.

EPA recognizes the reasonableness of Colorado's conclusion, specifically with regard to element 1 (significant contribution to nonattainment).[5] In addition, EPA notes that the highest monitored NO_2 design values in each state bordering Colorado are significantly below the NAAQS (see Table 2, below).[6] This fact further supports the State's contention that significant contribution to nonattainment or interference with maintenance of the NO_2 NAAQS from Colorado is very unlikely based on the lack of areas with high levels of NO_2. This is especially relevant for element 2 (interference with maintenance), because in addition to the lack of areas violating the NO_2 NAAQS, there are also no areas near the State approaching violation of the 2010 NO_2 NAAQS which might therefore be expected to have difficulty maintaining the standard.

TABLE 2—HIGHEST MONITORED 2010 NO_2 NAAQS DESIGN VALUES

State	2011–2013 Design value	Percent of NAAQS (100 ppb)
Kansas	65 ppb	65.
Nebraska	No Data	No Data.
New Mexico	41 ppb	41.
Oklahoma	54 ppb	54.
South Dakota	37 ppb	37.
Utah	66 ppb	66.
Wyoming	35 ppb	35.

* Source: *http://www.epa.gov/airtrends/values.html.*

In addition to the monitored levels of NO_2 in states bordering Colorado being well below the NAAQS, Colorado's highest design value from 2011–2013 was also significantly below this NAAQS (62 ppb).[7]

Based on all of these factors, EPA concurs with the State's conclusion that Colorado does not contribute significantly to nonattainment or interfere with maintenance of the 2010 NO_2 NAAQS in other states. EPA is therefore proposing to determine that Colorado's SIP includes adequate provisions to prohibit sources or other emission activities within the State from emitting NO_2 in amounts that will contribute significantly to nonattainment in or interfere with maintenance by any other state with respect specifically to the NO_2 NAAQS.

B. Evaluation of Interference With Measures To Prevent Significant Deterioration (PSD)

Colorado's certifications with regard to elements 3 and 4 of 110(a)(2)(D)(i) vary by pollutant. Each certification can be found in the docket for this action.

With regard to the PSD portion of section 110(a)(2)(D)(i)(II), this requirement may be met by a state's confirmation in an infrastructure SIP submission that new major sources and major modifications in the state are subject to a comprehensive EPA-approved PSD permitting program in the SIP that applies to all regulated NSR pollutants and that satisfies the requirements of EPA's PSD

[4] 2011 Memo at pg 8.

[5] EPA has not interpreted element 1 to literally mean contribution to designated nonattainment areas, and has applied this interpretation in comprehensive actions addressing elements 1 and 2 (See *e.g.,* Cross-State Air Pollution Rule, 76 FR 48208, August 8, 2011).

[6] EPA did not calculate a 2010 1-hour NO_2 design value in the state of Nebraska for the 2011–2013 design value period.

[7] *http://www.epa.gov/airtrends/values.html.*

implementation rule(s).[8] As noted in Section VI.3 of this proposed action, Colorado has such a program, and EPA is therefore proposing to approve Colorado's SIP for the 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS with respect to the requirement in section 110(a)(2)(C) to include a permit program in the SIP as required by part C of the Act.

As stated in the 2013 Memo, in-state sources not subject to PSD for any one or more of the pollutants subject to regulation under the CAA because they are in a nonattainment area for a NAAQS related to those particular pollutants may also have the potential to interfere with PSD in an attainment or unclassifiable area of another state. One way a state may satisfy element 3 with respect to these sources is by citing an air agency's EPA-approved nonattainment NSR provisions addressing any pollutants for which the state has designated nonattainment areas. Colorado has a SIP-approved nonattainment NSR program which ensures regulation of major sources and major modifications in nonattainment areas.[9]

As Colorado's SIP meets PSD requirements for all regulated NSR pollutants, and contains a fully approved nonattainment NSR program, EPA is proposing to approve the infrastructure SIP submission as meeting the applicable requirements of element 3 of section 110(a)(2)(D)(i) for the 2008 ozone, 2008 Pb and 2010 NO_2 NAAQS.

C. Evaluation of Interference With Measures To Protect Visibility

To determine whether the CAA section 110(a)(2)(D)(i)(II) requirement for visibility protection is satisfied, the SIP must address the potential for interference with visibility protection caused by the pollutant (including precursors) to which the new or revised NAAQS applies. An approved regional haze SIP that fully meets the regional haze requirements in 40 CFR 51.308 satisfies the 110(a)(2)(D)(i)(II) requirement for visibility protection as it ensures that emissions from the state will not interfere with measures required to be included in other state SIPs to protect visibility. In the absence of a fully approved regional haze SIP, a state can still make a demonstration that satisfies the visibility requirement section of 110(a)(2)(D)(i)(II).[10]

Colorado submitted a regional haze SIP to EPA on May 25, 2011. EPA approved Colorado's regional haze SIP on December 31, 2012 (77 FR 76871). In early 2013, WildEarth Guardians and the National Parks Conservation Association (NPCA) filed separate petitions for reconsideration of certain aspects of EPA's approval of the Colorado's regional haze SIP.[11] After these petitions were filed, a settlement agreement was entered into concerning the Craig Generating Station by the petitioners, EPA, CDPHE, and Tri-State Generation and Transmission Association, Inc., and filed with the court on July 10, 2014.[12] In accordance with the settlement agreement, EPA requested and the court granted a voluntary remand to EPA of the portions of EPA's December 2012 regional haze SIP approval that related to Craig Unit 1. Because of this remand, and because the additional controls at the Craig facility will be implemented through a revision to the Colorado regional haze SIP that EPA has not yet acted on, EPA cannot rely on this approval as automatically satisfying element 4.

EPA does, however, consider other aspects of our approval of Colorado's regional haze SIP to be sufficient to satisfy this requirement. Specifically, EPA found that Colorado met its 40 CFR 51.308(d)(3)(ii) requirements to include in its regional haze SIP all measures necessary to (1) obtain its share of the emission reductions needed to meet the reasonable progress goals for any other state's Class I area to which Colorado causes or contributes to visibility impairment, and; (2) ensure it has included all measures needed to achieve its apportionment of emission reduction obligations agreed upon through a regional planning process. Colorado participated in a regional planning process with Western Regional Air Partnership (WRAP). In the regional planning process, Colorado analyzed the WRAP modeling and determined that emissions from the State do not significantly impact other states' Class I areas.[13] Colorado accepted and incorporated the WRAP-developed visibility modeling into its regional haze SIP, and the SIP included the controls assumed in the modeling. For these reasons, EPA determined that Colorado had satisfied the Regional Haze Rule requirements for consultation and included controls in the SIP sufficient to address the relevant requirements related to impacts on Class I areas in other states. Therefore, we are proposing to approve the Colorado SIP as meeting the requirements of element 4 of CAA section 110(a)(2)(D)(i) for the 2008 ozone, 2008 Pb and 2010 NO_2 NAAQS.

5. Interstate and International transport provisions: CAA section 110(a)(2)(D)(ii) requires SIPs to include provisions ensuring compliance with the applicable requirements of CAA sections 126 and 115 (relating to interstate and international pollution abatement). Specifically, CAA section 126(a) requires new or modified major sources to notify neighboring states of potential impacts from the source.

Section 126(a) requires notification to affected, nearby states of major proposed new (or modified) sources. Sections 126(b) and (c) pertain to petitions by affected states to the Administrator of the U.S. EPA (Administrator) regarding sources violating the ''interstate transport'' provisions of section 110(a)(2)(D)(i). Section 115 similarly pertains to international transport of air pollution.

As required by 40 CFR 51.166(q)(2)(iv), Colorado's SIP-approved PSD program requires notice to states whose lands may be affected by the emissions of sources subject to PSD.[14] This suffices to meet the notice requirement of section 126(a).

Colorado has no pending obligations under sections 126(c) or 115(b); therefore, its SIP currently meets the requirements of those sections. In summary, the SIP meets the requirements of CAA section 110(a)(2)(D)(ii) for the 2008 ozone, 2008 Pb and 2010 NO_2 NAAQS.

6. Adequate resources: Section 110(a)(2)(E)(i) requires states to provide necessary assurances that the state will have adequate personnel, funding, and authority under state law to carry out the SIP (and is not prohibited by any provision of federal or state law from carrying out the SIP or portion thereof). Section 110(a)(2)(E)(ii) also requires each state to comply with the requirements respecting state boards under CAA section 128. Section 110(a)(2)(E)(iii) requires states to ''provide necessary assurances that, where the State has relied on a local or regional government, agency, or

[8] See 2013 Memo.

[9] See Colorado Regulation No. 3, Part D, Section V, which was most recently approved by EPA in a final rulemaking dated February 13, 2014 (79 FR 8632).

[10] See 2013 Memo. In addition, EPA approved the visibility requirement of 110(a)(2)(D)(i) for the 1997 Ozone and $PM_{2.5}$ NAAQS for Colorado before taking action on the State's regional haze SIP. 76 FR 22036 (April 20, 2011).

[11] WildEarth Guardians filed its petition on February 25, 2013, and NPCA filed its petition on March 1, 2013.

[12] This settlement agreement is included in the docket for this action; *see also* Proposed Settlement Agreement, 79 FR 47636 (Aug. 14, 2014).

[13] See our proposed rulemaking on the Colorado regional Haze SIP, 77 FR 18052, March 26, 2012.

[14] See Colorado Regulation 3, Part D. IV.A.1.

instrumentality for the implementation of any [SIP] provision, the State has responsibility for ensuring adequate implementation of such [SIP] provision.''

a. Sub-elements (i) and (iii): Adequate personnel, funding, and legal authority under state law to carry out its SIP, and related issues. Colorado revised statues, specifically the Colorado Air Pollution Prevention and Control Act (APPCA) Sections 25–7–105, 25–7–111, 42–4–301 to 42–4–316, 42–4–414 and Article 7 of Title 25, provide adequate authority for the State of Colorado APCD and AQCC to carry out its SIP obligations with respect to the 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS. The State receives Sections 103 and 105 grant funds through its Performance Partnership Grant along with required state matching funds to provide funding necessary to carry out Colorado's SIP requirements. The regulations cited by Colorado in their certifications and contained within this docket also provide the necessary assurances that the State has responsibility for adequate implementation of SIP provisions by local governments. Therefore, we propose to approve Colorado's SIP as meeting the requirements of section 110(a)(2)(E)(i) and (E)(iii) for the 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS.

b. Sub-element (ii): State boards. Section 110(a)(2)(E)(ii) requires each state's SIP to contain provisions that comply with the requirements of section 128 of the CAA. That provision contains two explicit requirements: (i) That any board or body which approves permits or enforcement orders under the CAA shall have at least a majority of members who represent the public interest and do not derive a significant portion of their income from persons subject to such permits and enforcement orders; and (ii) that any potential conflicts of interest by members of such board or body or the head of an executive agency with similar powers be adequately disclosed.[15]

On April 10, 2012 (77 FR 21453) EPA approved the Procedural Rules, Section 1.11.0, as adopted by the AQCC on January 16, 1998, into the Colorado SIP as meeting the requirements of section 128 of the Act. Section 1.11.0 specifies certain requirements regarding the composition of the AQCC and disclosure by its members of potential conflicts of interest. Details on how this portion of the Procedural Rules meets the requirements of section 128 are provided in our January 4, 2012 proposal notice (77 FR 235). In our April 10, 2012 action, we correspondingly approved Colorado's infrastructure SIP for the 1997 ozone NAAQS for element (E)(ii). Colorado's SIP continues to meet the requirements of section 110(a)(2)(E)(ii), and we propose to approve the infrastructure SIP for the 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS for this element.

7. Stationary source monitoring system: Section 110(a)(2)(F) requires:

(i) The installation, maintenance, and replacement of equipment, and the implementation of other necessary steps, by owners or operators of stationary sources to monitor emissions from such sources, (ii) Periodic reports on the nature and amounts of emissions and emissions-related data from such sources, and (iii) Correlation of such reports by the state agency with any emission limitations or standards established pursuant to the Act, which reports shall be available at reasonable times for public inspection.

The Colorado AQCC Regulations listed in the State's certifications (Regulations 1, 3, 7, and Common Provisions Regulation) and contained within this docket provide authority to establish a program for measurements and testing of sources, including requirements for sampling and testing. Air Pollutant Emission Notice (APEN) requirements are defined in Regulation 3 and requires stationary sources to report their emissions on a regular basis through APENs. Regulation 3 also requires for monitoring to be performed in accordance with EPA accepted procedures, and record keeping of air pollutants. Additionally, Regulation 3 provides for a permitting program that establishes emission limitations and standards. Emissions must be reported by sources to the state for correlation with applicable emissions limitations and standards. Monitoring may be required for both construction and operating permits.

Additionally, Colorado is required to submit emissions data to the EPA for purposes of the National Emissions Inventory (NEI). The NEI is the EPA's central repository for air emissions data. The EPA published the Air Emissions Reporting Rule (AERR) on December 5, 2008, which modified the requirements for collecting and reporting air emissions data (73 FR 76539). The AERR shortened the time states had to report emissions data from 17 to 12 months, giving states one calendar year to submit emissions data. All states are required to submit a comprehensive emissions inventory every three years and report emissions for certain larger sources annually through the EPA's online Emissions Inventory System. States report emissions data for the six criteria pollutants and their associated precursors—nitrogen oxides, sulfur dioxide, ammonia, lead, carbon monoxide, particulate matter, and volatile organic compounds. Many states also voluntarily report emissions of hazardous air pollutants. Colorado made its latest update to the NEI on December 31, 2014. EPA compiles the emissions data, supplementing it where necessary, and releases it to the general public through the Web site *http://www.epa.gov/ttn/chief/eiinformation.html.*

Based on the analysis above, we propose to approve the Colorado's SIP as meeting the requirements of CAA section 110(a)(2)(F) for the 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS.

8. Emergency powers: Section 110(a)(2)(G) of the CAA requires infrastructure SIPs to ''provide for authority comparable to that in [CAA section 303 [16]] and adequate contingency plans to implement such authority.''

Under CAA section 303, the Administrator has authority to bring suit to immediately restrain an air pollution source that presents an imminent and substantial endangerment to public health or welfare, or the environment. If such action may not practicably assure prompt protection, then the Administrator has authority to issue temporary administrative orders to protect the public health or welfare, or the environment, and such orders can be extended if EPA subsequently files a civil suit.

APPCA Sections 25–7–112 and 25–7–113 provide APCD with general emergency authority comparable to that in section 303 of the Act. APPCA section 25–7–112(1) provides the Division of Administration in the CDPHE with the authority to maintain civil actions over the sources of air pollution discharges that constitute ''a clear, present, and immediate danger to the environment or to the health of the public.'' Specifically, the Division can seek a ''temporary restraining order, temporary injunction, or permanent injunction as provided for in the Colorado rules of civil procedure'' (C.R.S. section 25–7–112(1)(b)). This

[15] EPA's proposed rule notice (79 FR 71040, Dec. 1, 2014) includes a discussion of the legislative history of how states could meet the requirements of CAA section 128.

[16] Discussion of the requirements for meeting CAA section 303 is provided in our notice of proposed rulemaking: Promulgation of State Implementation Plan Revisions; Infrastructure Requirements for the 1997 and 2006 $p.m._{2.5}$, 2008 Lead, 2008 Ozone, and 2010 NO_2 National Ambient Air Quality Standards; South Dakota (79 FR 71040, Dec. 1, 2014) under ''VI. Analysis of State Submittals, 8. Emergency powers.''

authority extends to discharges that constitute ''an immediate danger to the welfare of the public because such pollutants make habitation of residences or the conduct of businesses subjected to the pollutants extremely unhealthy or disruptive.'' (C.R.S. Section 25–7–113(1)).

These civil actions may be maintained ''in any district court of this state for the district in which the said activity or discharge is occurring.'' (C.R.S. Sections 25–7–112(1)(b); 25–7–113(1)(b)). Additionally, the action ''shall be given precedence over all other matters pending in such district court.'' (*Id*). As such, Colorado law provides statutory authority over sources of air pollution discharges that cause an ''immediate danger'' to public health, welfare, or the environment. This authority allows for the pursuit of immediate relief and provides precedence for such matters. Therefore, Colorado has comparable judicial authority to that provided to the Administrator in Section 303.

Similarly, APPCA section 25–7–112(1)(a) provides the Division of Administration in the CDPHE with the authority to issue ''cease-and-desist orders. . .requiring immediate discontinuance of such activity or the discharge of such pollutant into the atmosphere'' when the activity or discharge ''constitutes a clear, present, and immediate danger to the environment or to the health of the public.'' (C.R.S. Section 25–7–112(1)(a)). Further, ''upon receipt of such order, such person shall immediately discontinue such activity or discharge.'' (*Id*). This authority extends to discharges that constitute ''an immediate danger to the welfare of the public because such pollutants make habitation of residences or the conduct of businesses subjected to the pollutants extremely unhealthy or disruptive.'' (C.R.S. Section 25–7–113(1)).

These provisions also allow the Division to ''both issue such a cease-and-desist order and apply for any such restraining order or injunction'' (C.R.S. Sections 25–7–112(1)(c); 25–7–113(c)). Colorado law provides administrative authority over sources of air pollution discharges that cause an ''immediate danger'' to public health, welfare, or the environment. Furthermore, C.R.S. Sections 25–7–112(2)(b) allows the Governor to declare a state of air pollution emergency and take any and all actions necessary to protect the health of the public. This authority is comparable to that provided to the Administrator in Section 303.

States must also have adequate contingency plans adopted into their SIP to implement the air agency's emergency episode authority (as discussed above). This can be met can by submitting a plan that meets the applicable requirements of 40 CFR part 51, subpart H for the relevant NAAQS if the NAAQS is covered by those regulations. The Denver Emergency Episode Plan, applicable to the Denver metropolitan area, satisfies the requirements of 40 CFR part 51, subpart H (See 74 FR 47888). The SIP therefore meets the requirements of 110(a)(2)(G). Based on the above analysis, we propose approval of Colorado's SIP as meeting the requirements of CAA section 110(a)(2)(G) for the 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS.

9. Future SIP revisions: Section 110(a)(2)(H) requires that SIPs provide for revision of such plan: (i) From time to time as may be necessary to take account of revisions of such national primary or secondary ambient air quality standard or the availability of improved or more expeditious methods of attaining such standard, and (ii), except as provided in paragraph (3)(C), whenever the Administrator finds on the basis of information available to the Administrator that the SIP is substantially inadequate to attain the NAAQS which it implements or to otherwise comply with any additional requirements under this [Act].

Colorado's statutory provision at Colorado APPCA Sections 25–7–105(1)(a)(I) gives the AQCC sufficient authority to meet the requirements of 110(a)(2)(H). Therefore, we propose to approve Colorado's SIP as meeting the requirements of CAA section 110(a)(2)(H).

10. Consultation with government officials, public notification, PSD and visibility protection: Section 110(a)(2)(J) requires that each SIP ''meet the applicable requirements of section 121 of this title (relating to consultation), section 127 of this title (relating to public notification), and part C of this subchapter (relating to PSD of air quality and visibility protection).''

The State has demonstrated it has the authority and rules in place through its certifications (contained within this docket) to provide a process of consultation with general purpose local governments, designated organizations of elected officials of local governments and any Federal Land Manager having authority over federal land to which the SIP applies, consistent with the requirements of CAA section 121. Furthermore, EPA previously addressed the requirements of CAA section 127 for the Colorado SIP and determined public notification requirements are appropriate (45 FR 53147, Aug. 11, 1980).

As discussed above, the State has a SIP-approved PSD program that incorporates by reference the federal program at 40 CFR 52.21. EPA has further evaluated Colorado's SIP approved PSD program in this proposed action under element (C) and determined the State has satisfied the requirements of element 110(a)(2)(C), as noted above. Therefore, the State has also satisfied the requirements of element 110(a)(2)(J).

Finally, with regard to the applicable requirements for visibility protection, EPA recognizes states are subject to visibility and regional haze program requirements under part C of the Act. In the event of the establishment of a new NAAQS, however, the visibility and regional haze program requirements under part C do not change. Thus, we find that there are no applicable visibility requirements under section 110(a)(2)(J) when a new NAAQS becomes effective.

Based on the above analysis, we propose to approve the Colorado SIP as meeting the requirements of CAA section 110(a)(2)(J) for the 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS.

11. Air quality and modeling/data: Section 110(a)(2)(K) requires each SIP provide for: (i) The performance of such air quality modeling as the Administrator may prescribe for the purpose of predicting the effect on ambient air quality of any emissions of any air pollutant for which the Administrator has established a NAAQS, and (ii) the submission, upon request, of data related to such air quality modeling to the Administrator.

Colorado's Regulation 3 Part A.VIII (Technical Modeling and Monitoring Requirements) requires estimates of ambient air concentrations be based on applicable air quality models approved by EPA. Final approval for Regulation 3 Part A.VIII became effective February 20, 1997 (62 FR 2910). Additionally, Regulation 3 Part D, Section VI.C. requires the Division to transmit to the Administrator of the U.S. EPA a copy of each permit application relating to a major stationary source or major modification subject to this regulation, and provide notice of every action related to the consideration of such permit.

Colorado has broad authority to develop and implement an air quality control program that includes conducting air quality modeling to predict the effect on ambient air quality of any emissions of any air pollutant for which a NAAQS has been promulgated and provide that modeling data to the EPA. This broad authority can be found in 25–7–102, C.R.S., which requires that

emission control measures be evaluated against economic, environmental, energy and other impacts, and indirectly authorizes modeling activities.[17] Colorado also has broad authority to conduct modeling and submit supporting data to EPA to satisfy federal non-attainment area requirements (25–7–105, 25–7–205.1, 25–7–301, and 25–7–302, C.R.S.). In addition to statutory authority, all state implementation plans and revisions of such plans must be submitted to Colorado's Legislature for review providing another layer of review and authorization for submittal to EPA (25–7–133(1), C.R.S.). The State also has the authority to submit any modeling data to EPA upon request under the Colorado Open Records Act (24–72–201 to 24–72–309, C.R.S.).

As a result, the SIP provides for such air quality modeling as the Administrator has prescribed. Therefore, we propose to approve the Colorado SIP as meeting the CAA section 110(a)(2)(K) for the 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS.

12. Permitting fees: Section 110(a)(2)(L) requires SIPs to: Require the owner or operator of each major stationary source to pay to the permitting authority, as a condition of any permit required under this act, a fee sufficient to cover; (i) the reasonable costs of reviewing and acting upon any application for such a permit; and (ii) if the owner or operator receives a permit for such source, the reasonable costs of implementing and enforcing the terms and conditions of any such permit (not including any court costs or other costs associated with any enforcement action), until such fee requirement is superseded with respect to such sources by the Administrator's approval of a fee program under title V.

The State of Colorado requires the owner or operator of a major stationary source to pay the Division any fee necessary to cover the reasonable costs of reviewing and acting upon any permit application. The collection of fees is described in AQCC Regulation 3, Part A.

We also note that the State has an EPA approved title V permit program (60 FR 4563, Jan. 24, 1995) which provides for collection of permitting fees. Final approval of the title V operating permit program became effective October 16, 2000 (65 FR 49919). Interim approval of Colorado's title V operating permit program became effective February 23, 1995 (60 FR 4563). As discussed in the proposed interim approval of the title V program (59 FR 52123, October 14, 1994), the State demonstrated that the fees collected were sufficient to administer the program.

Therefore, based on the State's experience in relying on the collection of fees as described in AQCC Regulation 3, and the use of title V fees to implement and enforce PSD permits once they are incorporated into title V permits, we propose to approve the submissions as supplemented by the State for the 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS.

13. Consultation/participation by affected local entities: Section 110(a)(2)(M) requires states to provide for consultation and participation in SIP development by local political subdivisions affected by the SIP.

The statutory provisions cited in Colorado's SIP submittals (contained within this docket) meet the requirements of CAA section 110(a)(2)(M), so we propose to approve Colorado's SIP as meeting these requirements for the 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS.

VII. What action is EPA taking?

In this action, EPA is proposing to approve the following infrastructure elements for the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS: (A), (C) with respect to minor NSR and PSD requirements, (D)(i)(II) elements 3 and 4, (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M). EPA is proposing to approve element (B) for the 2008 Pb and 2008 ozone NAAQS and proposing to conditionally approve element (B) for the 2010 NO_2 NAAQS. Finally, EPA proposes approval of D(i)(I) elements 1 and 2 for the 2008 Pb and 2010 NO_2 NAAQS. EPA will act separately on infrastructure element (D)(i)(I), interstate transport elements 1 and 2 for the 2008 ozone NAAQS.

VIII. Statutory and Executive Orders Review

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations (42 U.S.C. 7410(k), 40 CFR 52.02(a)). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely approves some state law as meeting federal requirements and disapproves other state law because it does not meet federal requirements; this proposed action 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, Oct. 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, Aug. 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and,
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, Feb. 16, 1994).

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

List of Subjects in 40 CFR Part 52

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

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

[17] *See* Email from Robert True ''Response Requested for Element K on CO's iSIP'' April 6, 2015, available within docket.

Dated: May 13, 2015.

Shaun L. McGrath,

Regional Administrator, Region 8.

[FR Doc. 2015–13123 Filed 5–29–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2010–0304; FRL–9928–51–Region 8]

Approval and Promulgation of Air Quality Implementation Plans; Montana; Revisions to the Administrative Rules of Montana; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve State Implementation Plan (SIP) revisions submitted by the State of Montana on March 17, 2010, August 1, 2011, November 22, 2011, and September 19, 2014. The revisions are to the Administrative Rules of Montana (ARM) and include minor editorial and grammatical changes, updates to citations and references to federal and state laws and regulations, revisions to open burning rules, changes to the process for appealing air quality permits, and providing a process for revocation of air quality permits when owners cannot be found by mail. Also in this action, EPA is proposing to correct final rules pertaining to Montana's SIP. On January 29, 2010, EPA took direct final action to approve SIP revisions as submitted by the State of Montana on January 16, 2009 and May 4, 2009. EPA subsequently discovered an error in our January 29, 2010 direct final action related to ''incorporation by reference'' (IBR) materials and the associated regulatory text numbering. EPA is proposing to correct this error with today's action. This action is being taken under section 110 of the Clean Air Act (CAA).

DATES: Written comments must be received on or before July 1, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2010–0304, by one of the following methods:

- *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Email: fulton.abby@epa.gov.*
- *Fax:* (303) 312–6064 (please alert the individual listed in the **FOR FURTHER INFORMATION CONTACT** if you are faxing comments).
- *Mail:* Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mail Code 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129.
- *Hand Delivery:* Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mail Code 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129. Such deliveries are only accepted Monday through Friday, 8:00 a.m. to 4:30 p.m., excluding federal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R08–OAR–2010–0304. 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. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.* For additional instructions on submitting comments, go to section I, General Information, of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Air Program, Environmental Protection Agency (EPA), Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8:00 a.m. to 4:00 p.m., excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Abby Fulton, Air Program, U.S. Environmental Protection Agency (EPA), Region 8, Mail Code 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129, (303) 312–6563, *fulton.abby@epa.gov.*

SUPPLEMENTARY INFORMATION:

Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

(i) The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.

(ii) The initials *ARM* mean or refer to the Administrative Rules of Montana.

(iii) The initials *BACT* mean or refer to Best Available Control Technology.

(iv) The word or initials *Board* or *BER* mean or refer to the Montana Board of Environmental Review.

(v) The initials *CAMR* mean or refer to the Environmental Protection Agency's Clear Air Mercury Rule.

(vi) The initials *CBI* mean or refer to confidential business information.

(vii) The initials *CFR* mean or refer to the United States Code of Federal Regulations.

(viii) The initials *DEQ* mean or refer to the Department of Environmental Quality.

(ix) The words *EPA, we, us* or *our* mean or refer to the United States Environmental Protection Agency.

(x) The initials *IBR* mean or refer to Incorporate by Reference.

(xi) The initials *MCA* mean or refer to the Montana Code Annotated.

(xii) The initials *NAAQS* mean or refer to national ambient air quality standards.

(xiii) The initials *NESHAP* mean or refer to National Emission Standards for Hazardous Air Pollutants.

(xiv) The initials *NSPS* mean or refer to New Source Performance Standards.

(xv) The initials *SIP* mean or refer to State Implementation Plan.

(xvi) The word *State* means or refers to the State of Montana.

I. General Information

What should I consider as I prepare my comments for EPA?

1. *Submitting Confidential Business Information (CBI).* Do not submit CBI to EPA through *http://www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register**, date, and page number);
- Follow directions and organize your comments;
- Explain why you agree or disagree;
- Suggest alternatives and substitute language for your requested changes;
- Describe any assumptions and provide any technical information and/or data that you used;
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced;
- Provide specific examples to illustrate your concerns, and suggest alternatives;
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats; and
- Make sure to submit your comments by the comment period deadline identified.

II. Background

A. On March 17, 2010 the State of Montana submitted a SIP revision containing amendments to IBR current federal regulations and other material into air quality rules at ARM 17.8.102, 17.8.302, 17.8.767, 17.8.802, 17.8.822, 17.8.902, and 17.8.1002. The amendments update IBR dates, make minor editorial and grammatical changes, and delete references to EPA's Clean Air Mercury Rule (CAMR) which was vacated in February 2008. The Montana Board of Environmental Review (BER) adopted the amendments on October 2, 2009.

B. On August 1, 2011 the State submitted a SIP revision containing amendments to IBR current federal regulations and other material into air quality rules at ARM 17.8.102. The revisions update IBR dates and associated references, make minor editorial and grammatical changes, and delete the exclusion from IBR of 40 Code of Federal Regulations (CFR) part 60, subpart DDDD—Emissions Guidelines and Compliance Times for Commercial and Industrial Solid Waste Incineration Units. The BER adopted the amendments on January 28, 2011.

C. On November 22, 2011 Montana submitted a SIP revision containing amendments to ARM 17.8.604, 17.8.610, 17.8.612, 17.8.613, 17.8.614, 17.8.615, and 17.8.763. The amendments allow certain open burning to occur in areas other than where waste was generated, revise the process for appealing air quality permits, provide a process for revocation of air quality permits when owners cannot be found by mail, and make minor editorial and grammatical changes. The Board adopted the amendments on March 25, 2011.

D. On September 19, 2014 the State of Montana submitted a SIP revision containing amendments to IBR current federal regulations and other material into air quality rules at ARM 17.8.102. The amendments update IBR dates, make minor editorial and grammatical changes, and delete references to certain subparts of 40 CFR parts 60 and 63. The Montana BER adopted the amendments on May 30, 2014.

E. On January 26, 2010, EPA took direct final action (75 FR 3993) to approve revisions to ARM 17.8.102—Incorporation by Reference—Publication Dates, with a State effective date of October 26, 2007. In a subsequent action, EPA took final action on July 8, 2011 (76 FR 40237) and inadvertently approved revisions to ARM 17.8.102 with a state effective date of June 17, 2005. This action provides notice that language in ARM 17.8.102 with a State effective date of October 26, 2007 was in effect between January 26, 2010 and publication of this notice. A copy of ARM 17.8.102 effective October 26, 2007 is available within this docket.

F. On January 29, 2010, EPA published a direct final rule in the **Federal Register** approving Montana SIP revisions to the ARM. This action proposes to correct an error in the regulatory language in 40 CFR 52.1370(c) of EPA's January 29, 2010 direct final rule (75 FR 4698).

The State was delegated the authority for implementation and enforcement of National Emission Standards for Hazardous Air Pollutants (NESHAPs) through a **Federal Register** notice on May 11, 1995 (60 FR 25143) and New Source Performance Standards (NSPS) by letter on January 9, 2004 (69 FR 43371, July 20, 2004). When a delegation of authority is granted, EPA authorizes a state to implement and enforce a federal regulation. Prior to receiving delegation, NESHAPs and NSPS were enforced through Montana's SIP.[1] Through this process, the State IBR'd the Federal NESHAPs and NSPS in 40 CFR parts 60, 61, and 63 into its SIP-approved regulations. However, since receiving program delegation, many of the parts of the IBR referencing NESHAPs and NSPS in parts 60, 61, and 63 no longer need to be approved into Montana's SIP. EPA is working with the State to remove unnecessary parts of NESHAPs and NSPS from its SIP. These amendments will be reflected in a future **Federal Register** action. In the interim, we are proposing no action on any SIP revisions referencing 40 CFR parts 60, 61, and 63.

III. EPA's Review of the State of Montana's March 17, 2010; August 1, 2011; November 22, 2011; and September 19, 2014 Submittals, and CFR Correction

A. March 17, 2010 SIP Submittal

The State's March 17, 2010 SIP submittal contained amendments adopted by the State on October 2, 2009 (effective October 16, 2009) and includes the following types of amendments to the State's air quality rules: Revisions to its IBR of documents and other statutory references; and updated references to the July 1, 2008 edition of the CFR and the December 31, 2008 edition of the ARM. The revisions also make minor editorial and grammatical changes, and delete certain references to rules which have been vacated.

We are not acting on several of the State's amendments in the March 17, 2010 submittal that delete certain provisions from the State's rules because we did not approve those provisions into the SIP when they were part of a prior submittal from the State and they reference an NSPS in 40 CFR part 60. On November 1, 2006, the State submitted revisions to its SIP, including amendments to ARM 17.8.302, 17.8.767, 17.8.802, 17.8.902, and 17.8.1002. In our January 26, 2010 action (75 FR 3993), EPA did not act on revisions to ARM 17.8.302, 17.8.767, 17.8.802, 17.8.902, or 17.8.1002 because the revisions

[1] *See* Douglas M. Ski, Chief of the Air Programs Branch, EPA Region 8, Memorandum to Jeffery T. Chaffe, Chief of the Montana Air Quality Bureau (October 9, 1991).

referenced CAMR which was vacated by the U.S. Court of Appeals for the D.C. Circuit on February 8, 2008 (*see New Jersey* v. *EPA,* 517 F. 3d 574).

In its March 17, 2010 submission, the State revisions delete references to CAMR in ARM 17.8.302(1)(a)(ii), 17.8.767(1)(c), 17.8.802(1)(d), 17.8.902(1)(a), 17.8.1002(1)(a). Since EPA did not act on revisions to these sections of the ARM in our January 26, 2010 action, references to CAMR were never approved into Montana's SIP. Furthermore, as explained in the ''Background'' section of this notice, we are proposing no action on revisions referencing 40 CFR parts 60, 61, and 63. Therefore, EPA is proposing no action on the 2010 revisions to ARM 17.8.302(1)(a)(ii), 17.8.767(1)(c), 17.8.802(1)(d), 17.8.902(1)(a), and 17.8.1002(1)(a).

The March 17, 2010 revisions to ARM 17.8.102(1), 17.8.102(1)(a), and 17.8.102(1)(c) make minor grammatical changes and update the citations and references to federal law and State rules. In subsequent SIP submittals dated August 1, 2011 and September 19, 2014, the State again updates IBR publication dates. We therefore propose to act on revisions to ARM 17.8.102(1)(a), and 17.8.102(1)(c) from the September 19, 2014 submittal, as discussed below, and to approve the grammatical changes to ARM 17.8.102(1) from the March 17, 2010 submittal. Since the March 17, 2010 publication date revisions to these three rules were superseded by the August 1, 2011 and September 19, 2014 submittals, we are not acting on the publication date revisions in the March 17, 2010 submittal.

The March 2010 submittal also makes minor editorial and grammatical changes to ARM 17.8.102(2), 17.8.102(2)(a), and 17.8.102(3). ARM 17.8.102(2) and (3) list subparts of NSPS at 40 CFR part 60 and NESHAPs at 40 CFR part 63 which are excluded from IBR. We therefore propose no action on the revisions to ARM 17.8.102(2), 17.8.102(2)(a), and 17.8.102(3) from the August 1, 2011 submittal.

Finally, the submittal deletes ARM 17.8.802(1)(c) and 17.8.822(9), which require compliance with the ambient monitoring requirements of 40 CFR part 58, Appendix B. EPA proposes to approve revisions to ARM 17.8.802(1)(c) and 17.8.822(9) because that appendix no longer exists.

B. August 1, 2011 SIP Submittal

The State's August 1, 2011 SIP submittal contained amendments adopted by the State on January 28, 2011 (effective February 11, 2011) and includes the following types of amendments to the State's air quality rules: Revisions to its IBR of documents and other statutory references contained in the State's air quality rules; an updated reference to the July 1, 2009 edition of the CFR; and updated references to the 2006 edition of the United States Code and Supplement II (2009), and the December 31, 2009 edition of the ARM. The revisions also make minor editorial and grammatical changes, and delete references to a rule which has been vacated.

The August 1, 2011 revisions to ARM 17.8.102(1)(a), 17.8.102(1)(b), and 17.8.102(1)(c) update the citations and references to federal law and State rules. In a subsequent SIP submittal dated September 19, 2014, the State again updates IBR publication dates. We therefore propose to act on revisions to ARM 17.8.102(1)(a), 17.8.102(1)(b), and 17.8.102(1)(c) from the September 19, 2014 submittal, as discussed below. Since the August 1, 2011 publication date revisions to these three rules were superseded by the September 19, 2014 submittals, we are not acting on the publication date revisions in the August 1, 2011 submittal.

Additionally, the August 1, 2011 revisions makes a minor editorial change to ARM 17.8.102(3)(b) which excludes 40 CFR part 63, subpart KKKKK, National Emission Standards for Hazardous Air Pollutants for Clay Ceramics Manufacturing from IBR and deletes ARM 17.8.102(3)(d) which references portions of 40 CFR part 63, subpart DDDD—NESHAP for Plywood and Composite Wood Products. As previously discussed, we are not acting on revisions referencing 40 CFR parts 60 and 61, and therefore propose no action on ARM 17.8.102(3)(b) and 17.8.103(d).

C. November 22, 2011 SIP Submittal

The State's November 22, 2011 SIP submittal contained amendments adopted by the State on March 25, 2011 (effective April 15, 2011) and includes the following types of amendments to the State's air quality rules: Revisions to open burning rules regarding burning locations, permit appeal processes, grammatical changes, and revisions to the notification process of intent to revoke Montana Air Quality Permits.

Revisions to open burning rules in ARM section 17.8.604 specify the circumstances under which moving wood waste from the location where it was generated and burning it elsewhere may occur. The purpose of the revisions are to provide an exception to the general prohibition to allow wood waste generated in areas where burning would be unwise (*e.g.,* where burning wood waste on the premises where it is generated would produce unacceptable amounts of smoke that could cause or contribute to a violation of the National Ambient Air Quality Standards (NAAQS)) to be moved to areas where the burning could take place under conditions protective of the NAAQS and other conditions applicable to open burning.

In our August 24, 2006 final rule (71 FR 49999), we took no action on revisions to ARM 17.8.604(1)(a) that were submitted by the State on April 18, 2003 because language used in the rule revision was considered a department discretion. However, the State's November 22, 2011 submittal removes previous discretionary language of ''or unless approval is granted by the department on a case by case basis'' from its April 18, 2003 submittal and replaces it with criteria that the department applies when determining whether to issue a permit that allows for burning of any wood waste at a location other than where the wood waste was generated. The revisions ensure waste that is moved from the premises where it is generated is still prohibited material and may not be burned unless it is conducted pursuant to a landfill or conditional open burning permit issued by the department. For conditional air quality open burning, the State's rules require that the department only issue a permit under its rules if the open burning will not cause or contribute to a violation of the NAAQS and that the open burn conform to Best Available Control Technology (BACT) (ARM 17.8.612). Among other things, BACT also requires that these additional categories only burn during the time periods specified by the department (ARM 17.8.601(1)). The revisions also ensure the movement and burning is only an option for wood that is not already described as prohibited and ensure other methods of disposal are considered.

In our July 20, 2004 proposed notice (69 FR 43373) we explained that the proposed changes would not impact the stringency of the rule. In a letter to EPA dated August 19, 2004, the State clarified the intent of proposed changes to ARM 17.8.604(1)(a) stating that the purpose is to ''. . . allow open burning of material moved to an alternative site for purposes of better attaining and maintaining the NAAQS.'' ARM 17.8.604(1)(a) further allows ''. . . movement of material for open burning to locations that minimize health effects caused by exposure to smoke emissions. For example, when municipalities experience massive tree damage, disposal of material by open burning within city limits would expose

populations to smoke emissions. However, if material is relocated to an alternate site, populations are better protected from adverse health effects caused by exposure to smoke emissions'' (comment letter from Jan Sensibaugh, Director, Montana Department of Environmental Quality (DEQ) to EPA Air & Radiation Program Director Richard Long, contained within this docket).

Section 110(l) of the CAA states that a SIP revision cannot be approved if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress towards attainment of the NAAQS or any other applicable requirements of the Act. The proposed revisions to ARM 17.8.604(1) do not interfere with the maintenance of the NAAQS or any other applicable requirement of the Act. The November 22, 2011 submittal revises the open burning rules; however, as discussed earlier, we do not believe the changes will impact the NAAQS. Therefore, section 110(l) requirements are satisfied and we consequently propose to approve revisions to ARM 17.8.604(1)(a).

We propose to approve the revision to ARM 17.8.610(2) which corrects a grammatical error.

Revisions to ARM 17.8.612, 17.8.613, 17.8.614, and 17.8.615 reflect the Montana Legislature's revision of the process for appealing air quality permits pursuant to 75–2–211, Montana Code Annotated (MCA). The 2003 Legislature amended 75–2–211, MCA, to eliminate an automatic stay of the department's decision to issue a permit upon a permit appeal. Instead, during a 15-day delay before the department decision on the permit application becomes final, a permit decision may be stayed only following a petition and a finding that the person requesting the stay is entitled to the relief demanded in the request for hearing or that continuation of the permit would cause the petitioner great or irreparable injury. After 15 days, the department's decision cannot be appealed. If a stay is granted, but the appeal ultimately fails, the petitioner is liable for costs and damages to the permit applicant.

On March 11, 2003, EPA mailed a memorandum to the Director of the Montana DEQ [2] which expressed potential concern with legislation (including revisions to 75–2–211, MCA) pending in the Montana Legislature. As outlined in the memo, EPA was concerned that the proposed legislation had the potential to create major impediments to the public's ability to challenge air permits in state court as required by the CAA. An important consideration before EPA approves programs under the CAA is that the state must provide the same opportunity for judicial review of the air permitting actions in state court as would be available in federal court. The proposed bill (HB No. 700, available within this docket) contained provisions which would have required citizens and organizations to file for a preliminary injunction and then post a bond if such injunction was granted. The appealing party's bond required coverage of the permittee's costs of delay. Another provision required the person challenging the permit to indemnify the permittee for the same items covered in the bond. However, this language (*see* HB No. 700, Section 1. 75–2–211.(11)(d) and (e) contained within this docket) was struck from the legislation prior to approval.

We therefore conclude that the 2003 revisions made to 75–2–211, MCA (contained within this docket) do not conflict with the CAA requirements for judicial review of air permitting actions (*see* 42 U.S.C. 7607(b) [3] and 7607(d) [4]) and consequently propose to approve revisions to 17.8.612(10) and (11), 17.8.613(8) and (9), 17.8.614(8) and (9), and 17.8.615(6) and (7). Finally, revision to ARM 17.8.763 provides a process for notice by publication of the department's intent to revoke a Montana Air Quality Permit issued under Title 17, chapter 8, subchapter 7 when an owner or operator cannot be found for service by certified mail. We propose to approve the revision to ARM 17.8.763(3).

D. September 19, 2014 SIP Submittal

The State's September 19, 2014 SIP submittal contained amendments adopted by the State on May 30, 2014 (effective June 12, 2014) and includes the following types of amendments to the State's air quality rules: Revisions to its IBR of documents and other statutory references contained in the State's air quality rules; an updated reference to the July 1, 2013 edition of the CFR; and an updated reference to the 2012 edition of the United States Code as it existed on December 31, 2013. The revisions also make minor editorial and grammatical changes; delete references to NSPS and NESHAPs which are excluded from IBR; delete references to a rule which has been vacated; and add information on how to obtain IBR materials referenced in the ARM.

The September 19, 2014 revisions to ARM 17.8.102(1)(a), 17.8.102(1)(b), and 17.8.102(1)(c) update the citations and references to federal law and State rules. We propose to approve these revisions.

The September 19, 2014 revisions delete ARM 17.8.102(2), 17.8.102(2)(a), and 17.8.102(2)(b) which reference subparts of 40 CFR part 60 (NSPS) that are excluded from IBR. The revisions also make a minor editorial change to ARM 17.8.102(3); delete certain language in ARM 17.8.102(3)(a) and ARM 17.8.102(3)(b) which references 40 CFR part 63, subpart JJJJ, NESHAP for Brick and Structural Clay Products Manufacturing and subpart KKKK, NESHAP for Clay Ceramics Manufacturing, respectively; and delete ARM 17.8.102(3)(c) which references 40 CFR part 63, subpart DDDDD, NESHAP for Industrial, Commercial, and Institutional Boilers and Process Heaters. We propose no action on these revisions since they are in reference to 40 CFR parts 60 and 63.

Finally, the September 19, 2014 revisions add ARM 17.8.102(3) and 17.8.102(4)(a) through (d) which includes information on how to obtain a copy of materials incorporated by reference in this chapter of the ARM and copies of federal materials. We propose to approve language added to ARM 17.8.102(3) and 17.8.102(4)(a) through (d).

Proposed Correction

In the direct final rule published in the **Federal Register** on January 29, 2010 (75 FR 4698), on page 4700, third column, we propose to correct the amendatory instruction 2, in the second line, ''. . . adding paragraph (c) (68) . . .'' to read: ''. . . Adding paragraph (c) (69) . . ..''; and also propose the conforming change in the regulatory text, changing paragraph (c)(68) to (c)(69). This proposed change is necessary because of the inadvertent error made to this regulatory language in our action at 75 FR 4698.

[2] *See* Stephen S. Tuber, Acting Assistant Regional Administrator for the Office of Partnerships and Regulatory Assistance, Memorandum to Jan Sensibaugh, Director of Montana Department of Environmental Quality (March 11, 2003).

[3] The Environmental Appeals Board Practice Manual, EPA, (September 2010) *http://www.epa.gov/eab/pmanual.pdf.*

[4] 42 U.S.C. 7607(d)(7)(B) states: ''Only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review . . .'' ''If the Administrator refuses to convene such a proceeding, such person may seek review of such refusal in the United States court of appeals for the appropriate circuit (as provided in subsection (b) of this section). Such reconsideration shall not postpone the effectiveness of the rule. The effectiveness of the rule may be stayed during such reconsideration, however, by the Administrator or the court for a period not to exceed three months.''

IV. What action is EPA taking?

EPA is proposing to approve grammatical changes made to ARM 17.8.102(1), and all revisions of 17.8.802(1)(c) and 17.8.822(9) from the March 17, 2010 submittal. We propose to approve November 22, 2011 revisions to ARM 17.8.604(1)(a),17.8.610(2), 17.8.612(10) and (11), 17.8.613(8) and (9), 17.8.614(8) and (9), 17.8.615(6) and (7), and 17.8.763(3). We propose to approve the September 19, 2014 submittal's citations and references to federal law and State rules superseding and replacing all previous versions of ARM 17.8.102(1)(a), 17.8.102(1)(b), and 17.8.102(1)(c). Previous submittals were received on March 17, 2010 and August 1, 2011. We also propose to approve language added to ARM 17.8.102(3) and 17.8.102(4)(a) through (d) from the September 19, 2014 submittal. Our action also provides notice that language in ARM 17.8.102 was in effect between January 16, 2010 and publication of this notice. Finally, EPA proposes to correct erroneous amendatory instructions published in the **Federal Register** on January 29, 2010 (75 FR 4698).

V. Statutory and Executive Orders Review

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the Administrative Rules of Montana regarding citations and references to federal and State laws and regulations; open burning rules; air quality permits appeal process; and revocation of air quality permits discussed in section III, *EPA's Review of the State of Montana's March 17, 2010; August 1, 2011; November 22, 2011; and September 19, 2014 Submittals, and CFR Correction,* of this preamble. The EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations (42 U.S.C. 7410(k), 40 CFR 52.02(a)). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely approves some state law as meeting federal requirements and disapproves other state law because it does not meet federal requirements; this proposed action 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).

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

List of Subjects in 40 CFR Part 52

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

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

Dated: May 13, 2015.

Shaun L. McGrath,

Regional Administrator, Region 8.

[FR Doc. 2015–13129 Filed 5–29–15; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 97

[FRL–9928–49–OAR]

Availability of Data on Allocations of Cross-State Air Pollution Rule Allowances From New Unit Set-Asides for the 2015 Compliance Year

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of data availability (NODA).

SUMMARY: The Environmental Protection Agency (EPA) is providing notice of the availability of preliminary calculations of emission allowance allocations to certain units under the Cross-State Air Pollution Rule (CSAPR). Under the CSAPR federal implementation plans (FIPs), portions of each covered state's annual emissions budgets for each of the four CSAPR emissions trading programs are reserved for allocation to electricity generating units that commenced commercial operation on or after January 1, 2010 (new units) and certain other units not otherwise obtaining allowance allocations under the FIPs. The quantities of allowances allocated to eligible units from each new unit set-aside (NUSA) under the FIPs are calculated in an annual one- or two-round allocation process. EPA has completed preliminary calculations for the first round of NUSA allowance allocations for the 2015 compliance year and has posted spreadsheets containing the calculations on EPA's Web site. EPA will consider timely objections to the preliminary calculations (including objections concerning the identification of units eligible for allocations) and will promulgate a notice responding to any such objections no later than August 1, 2015, the deadline for recording the first-round allocations in sources' Allowance Management System accounts. This notice may concern CSAPR-affected units in the following states: Alabama, Arkansas, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Jersey, New

York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Virginia, West Virginia, and Wisconsin.

DATES: Objections to the information referenced in this notice must be received on or before July 1, 2015.

ADDRESSES: Submit your objections via email to *CSAPR_NUSA@epa.gov.* Include ''2015 NUSA allocations'' in the email subject line and include your name, title, affiliation, address, phone number, and email address in the body of the email.

FOR FURTHER INFORMATION CONTACT: Questions concerning this action should be addressed to Robert Miller at (202) 343–9077 or *miller.robertl@epa.gov* or Kenon Smith at (202) 343–9164 or *smith.kenon@epa.gov.*

SUPPLEMENTARY INFORMATION: Under the CSAPR FIPs, the mechanisms by which initial allocations of emission allowances are determined differ for ''existing'' and ''new'' units. For ''existing'' units—that is, units commencing commercial operation before January 1, 2010—the specific amounts of CSAPR FIP allowance allocations for all compliance years have been established through rulemaking. EPA has announced the availability of spreadsheets showing the CSAPR FIP allowance allocations to existing units in previous notices.[1]

''New'' units—that is, units commencing commercial operation on or after January 1, 2010—as well as certain older units that would not otherwise obtain FIP allowance allocations do not have pre-established allowance allocations. Instead, the CSAPR FIPs reserve a portion of each state's total annual emissions budget for each CSAPR emissions trading program as a new unit set-aside (NUSA)[2] and establish an annual process for allocating NUSA allowances to eligible units. States with Indian country within their borders have separate Indian country NUSAs. The annual process for allocating allowances from the NUSAs and Indian country NUSAs to eligible units is set forth in the CSAPR regulations at 40 CFR 97.411(b) and 97.412 (NO_X Annual Trading Program), 97.511(b) and 97.512 (NO_X Ozone Season Trading Program), 97.611(b) and 97.612 (SO_2 Group 1 Trading Program), and 97.711(b) and 97.712 (SO_2 Group 2 Trading Program). Each NUSA allowance allocation process involves up to two rounds of allocations to new units followed by the allocation to existing units of any allowances not allocated to new units. EPA provides public notice at certain points in the process. This notice concerns preliminary calculations for the first round of NUSA allowance allocations for the 2015 compliance year.[3]

The units eligible to receive first-round NUSA allocations are defined in §§ 97.412(a)(1), 97.512(a)(1), 97.612(a)(1), and 97.712(a)(1). Generally, eligible units include any CSAPR–affected unit that has not been allocated allowances as an existing unit as well as certain units that have been allocated allowances as existing units but whose allocations have been deducted or not recorded because of corrections or multi-year breaks in operations. EPA notes that a valid allowance allocation may consist of zero allowances; thus, an existing unit specifically allocated zero allowances in the spreadsheet of CSAPR FIP allowance allocations to existing units is generally ineligible to receive a NUSA allowance allocation.

The quantity of allowances to be allocated through the 2015 NUSA allowance allocation process for each state and emissions trading program is generally the state's 2015 emissions budget less the sum of (1) the total of the 2015 CSAPR FIP allowance allocations to existing units and (2) the amount of the 2015 Indian country NUSA, if any.[4] The amounts of NUSA allowances may be increased in certain circumstances as set forth in §§ 97.412(a)(2), 97.512(a)(2), 97.612(a)(2), and 97.712(a)(2).

The amounts of first-round allocations to eligible units from each NUSA are calculated according to the procedures set forth in §§ 97.412(a)(3)–(7) and (12), 97.512(a)(3)–(7) and (12), 97.612(a)(3)–(7) and (12), and 97.712(a)(3)–(7) and (12). Generally, the procedures call for each eligible unit to receive a first-round 2015 NUSA allocation equal to its 2014 emissions as reported under 40 CFR part 75 unless the total of such allocations to all eligible units would exceed the amount of allowances in the NUSA, in which case the allocations are reduced on a pro-rata basis.[5]

EPA notes that an allocation or lack of allocation of allowances to a given EGU does not constitute a determination that CSAPR does or does not apply to the EGU. EPA also notes that allocations are subject to potential correction.

The detailed unit-by-unit data and preliminary allowance allocation calculations are set forth in Excel spreadsheets titled ''CSAPR_NUSA_2015_NO_X_Annual_1st_Round_Prelim_Data'', ''CSAPR_NUSA_2015_NO_X_OS_1st_Round_Prelim_Data'', and ''CSAPR_NUSA_2015_SO_2_1st_Round_Prelim_Data,'' available on EPA's Web site at *http://www.epa.gov/crossstaterule/actions.html.* The three spreadsheets show EPA's initial determinations of 2015 NUSA allocations for new units subject to the CSAPR NO_X Annual, NO_X Ozone Season, and SO_2 (Group 1 and Group 2) trading programs, respectively. Each of the spreadsheets contains a separate worksheet for each state covered by that program showing, for each unit identified as eligible for a first-round NUSA allocation, (1) the unit's emissions in the 2014 control period (annual or ozone season as applicable), (2) the maximum first-round 2015 NUSA allowance allocation for which the unit is eligible (typically the unit's emissions in the 2014 control period), (3) various adjustments to the unit's maximum allocation, many of which are necessary only if the NUSA pool is oversubscribed, and (4) the preliminary calculation of the unit's first-round 2015 NUSA allowance allocation.

Each state worksheet also contains a summary showing (1) the quantity of allowances initially available in that state's 2015 NUSA, (2) the sum of the

[1] The latest spreadsheet of CSAPR FIP allowance allocations to existing units, updated in 2014 to reflect changes to CSAPR's implementation schedule but with allocation amounts unchanged since June 2012, is available at *http://www.epa.gov/crossstaterule/actions.html. See* Availability of Data on Allocations of Cross-State Air Pollution Rule Allowances to Existing Electricity Generating Units, 79 FR 71674 (December 3, 2014).

[2] The NUSA amounts range from two percent to eight percent of the respective state budgets. The variation in percentages reflects differences among states in the quantities of emission allowances projected to be required by known new units at the time the budgets were set or amended.

[3] At this time, EPA is not aware of any unit eligible for a first-round allocation from any Indian country NUSA.

[4] The quantities of allowances to be allocated through the NUSA allowance allocation process may differ slightly from the NUSA amounts set forth in §§ 97.410(a), 97.510(a), 97.610(a), and 97.710(a) because of rounding in the spreadsheet of CSAPR FIP allowance allocations to existing units.

[5] Subsequent allocations of any allowances remaining in any 2015 NUSA after first-round allocations will be addressed in future notices. Any such allocations will be made according to the procedures set forth in §§ 97.412(a)(9)–(10) and (12), 97.512(a)(9)–(10) and (12), 97.612(a)(9)–(10) and (12), and 97.712(a)(9)–(10) and (12). Generally, new units that commenced commercial operations in 2014 or 2015 will receive second-round 2015 NUSA allocations sufficient to bring the totals of their first- and second-round allocations up to their 2015 emissions as reported under 40 CFR part 75 unless the total of such second-round allocations for all eligible units would exceed the remaining amount of allowances in the NUSA, in which case the second-round allocations will be reduced on a pro-rata basis. Any allowances remaining in any NUSA after second-round allocations to new units—along with any allowances remaining in any corresponding Indian country NUSA—will be allocated to the state's existing units in proportion to their respective 2015 CSAPR FIP allocations of non-NUSA allowances.

first-round 2015 NUSA allowance allocations that will be made to new units in that state, assuming there are no corrections to the data, and (3) the quantity of allowances that would remain in the 2015 NUSA for use in second-round allocations to new units (or ultimately for allocation to existing units), again assuming there are no corrections to the data.

Objections should be strictly limited to the data and calculations upon which the NUSA allowance allocations are based and should be emailed to the address identified in **ADDRESSES**. Objections must include: (1) Precise identification of the specific data and/or calculations the commenter believes are inaccurate, (2) new proposed data and/or calculations upon which the commenter believes EPA should rely instead to determine allowance allocations, and (3) the reasons why EPA should rely on the commenter's proposed data and/or calculations and not the data referenced in this notice.

Authority: 40 CFR 97.411(b), 97.511(b), 97.611(b), and 97.711(b).

Dated: May 22, 2015.

Reid P. Harvey,

Director, Clean Air Markets Division.

[FR Doc. 2015–13031 Filed 5–29–15; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R2–ES–2015–0030; FF09E42000 156 FXES11130900000]

Endangered and Threatened Wildlife and Plants; 90-Day Finding on a Petition To Remove the Bone Cave Harvestman (Texella reyesi) From the List of Endangered and Threatened Wildlife

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of 90-day petition finding.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce a 90-day finding on a petition to remove the Bone Cave harvestman (*Texella reyesi*) from the List of Endangered and Threatened Wildlife under the Endangered Species Act of 1973, as amended (Act). Based on our review, we find that the petition does not present substantial scientific or commercial information indicating that the petitioned action may be warranted. Therefore, we are not initiating a status review in response to this petition. However, we ask the public to submit to us any new information that becomes available concerning the status of, or threats to, the Bone Cave harvestman or its habitat at any time.

DATES: The finding announced in this document was made on June 1, 2015.

ADDRESSES: Copies of the petition are available in the docket associated with this notice at *http://www.regulations.gov* and at *http://fws.gov/southwest/es/austintexas/* or upon request from the Field Supervisor of the Austin Ecological Services Field Office, 10711 Burnet Road, Suite 200, Austin, TX 78758.

FOR FURTHER INFORMATION CONTACT: Adam Zerrenner, Field Supervisor, Austin Ecological Services Field Office, 10711 Burnet Road, Suite 200, Austin, TX 78758; by telephone at 512–490–0057; or by facsimile at 512–490–0974. If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

Section 4(b)(3)(A) of the Act requires that we make a finding on whether a petition to list, delist, or reclassify a species presents substantial scientific or commercial information indicating that the petitioned action may be warranted. We are to base this finding on information provided in the petition, supporting information submitted with the petition, and information otherwise available in our files. To the maximum extent practicable, we are to make this finding within 90 days of our receipt of the petition and publish our notice of the finding promptly in the **Federal Register**.

Our standard for substantial scientific or commercial information within the Code of Federal Regulations (CFR) with regard to a 90-day petition finding is ''that amount of information that would lead a reasonable person to believe that the measure proposed in the petition may be warranted'' (50 CFR 424.14(b)(1)). If we find that substantial scientific or commercial information was presented, we are required to promptly conduct a species status review, which we subsequently summarize in a 12-month finding.

Petition History

On June 2, 2014, we received a petition from John Yearwood, Kathryn Heidemann, Charles and Cheryl Shell, the Walter Sidney Shell Management Trust, the American Stewards of Liberty, and Steven W. Carothers requesting that we remove the endangered Bone Cave harvestman from the Federal lists of endangered and threatened species. The petition clearly identified itself as a petition and included the requisite identification information for the petitioners, as required in 50 CFR 424.14(a). This finding addresses the petition.

Previous Federal Actions

The Bone Cave harvestman was originally listed as endangered on September 16, 1988 (53 FR 36029). In an August 18, 1993, **Federal Register** document (58 FR 43818), the Service gave the Bone Cave harvestman protection under the Act as a separate species. It had previously been listed as endangered as a part of the Bee Creek Cave harvestman (*Texella reddelli*), which was subsequently re-classified into two species, and this final rule set forth technical corrections to ensure that the species continued to receive protection under the Act. On March 14, 1994, we published a 90-day finding (59 FR 11755) on a petition to delist the Bone Cave harvestman in which we found that the petition did not present substantial scientific or commercial information indicating that the petitioned action may have been warranted. A draft recovery plan was available for public review and comment on June 7, 1993, and a final recovery plan was published on August 25, 1994 (Service 1994). On December 4, 2009, we completed a 5-year review of the Bone Cave harvestman, which recommended that the species remain listed as endangered (Service 2009).

Species Information

For information on the biology and life history of the Bone Cave harvestman, see the final rule listing this species (53 FR 36029), the Endangered Karst Invertebrates Recovery Plan for Travis and Williamson Counties (Service 1994), and the 5-year Status Review for the Bone Cave Harvestman (Service 2009), all posted at *http://ecos.fws.gov/speciesProfile/profile/speciesProfile.action?spcode=J009*. For information on preserve design and management for karst invertebrate species conservation, see the Karst Preserve Design Recommendations (Service 2012) and the Karst Preserve Management and Monitoring Recommendations (Service 2014) posted at *http://www.fws.gov/southwest/es/AustinTexas/ESA_Sp_KarstInverts.html.*

Evaluation of Information for This Finding

Under section 3(16) of the Act, we may consider for listing any species, including subspecies, of fish, or wildlife, or plants, and any distinct population segment (DPS) of any species of vertebrate fish or wildlife that interbreeds when mature (16 U.S.C. 1532(16)). Such entities are listed under the Act if we determine that they meet the definition of an endangered or threatened species.

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations at 50 CFR 424 set forth the procedures for adding a species to, or removing a species from, the lists of endangered and threatened species. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1) of the Act:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

We must consider these same five factors in delisting a species. We may delist a species according to 50 CFR 424.11(d) if the best available scientific and commercial data indicate that the species is neither endangered nor threatened for the following reasons:

(1) The species is extinct;

(2) the species is recovered; or

(3) the original data for classification were in error. According to 50 CFR 424.11(d)(3), a species may be delisted when subsequent investigations ''show that the best scientific and commercial data available when the species was listed, or the interpretation of such data, were in error.''

In making this 90-day finding, we evaluated whether the petition presented substantial information indicating that the petitioned action (delisting) may be warranted.

The petition did not assert that the Bone Cave harvestman is extinct, nor do we have information in our files indicating that the species is extinct.

The petition asserted that new information indicates that the original data, or our interpretation of the data, used in the listing of this species were in error. The petition also states that significant conservation has been put in place since the species was listed, such that the species is recovered.

In 2009, we conducted a 5-year status review of the Bone Cave harvestman (Service 2009). The purpose of a 5-year status review is to evaluate whether or not the species' status has changed since it was listed (or since the most recent 5-year review). Based on a 5-year review, we recommend whether the species should be removed from the lists of endangered and threatened species, be changed in status from endangered to threatened, or be changed in status from threatened to endangered. As part of the 2009 Bone Cave harvestman review, we evaluated whether the species had met the recovery criteria laid out in the species' recovery plan (Service 1994, pp. 86–89).

Our recovery handbook (Service 2010) points out that recovery criteria should address the biodiversity principles of resiliency, redundancy, and representation (Schaffer and Stein 2000).

Resiliency is defined as the ability of a species to persist through severe hardships or stochastic events (Tear *et al.* 2005, p. 841). A variety of factors contribute to a species' resiliency. These can include how sensitive the species is to disturbances or stressors in its environment, how often they reproduce and how many young they have, and their specific habitat needs. A species' resiliency can also be affected by the resiliency of individual populations and the number of populations and their distribution across the landscape. Protecting multiple populations and variation of a species across its range may contribute to its resiliency, especially if some populations or habitats are more susceptible or better adapted to certain threats than others (Service and NOAA 2011, p. 76994). The ability of individuals from populations to disperse and recolonize an area that has been extirpated may also influence the species' resiliency. As population size and habitat quality increase, the population's ability to persist through periodic hardships also increases. Healthy populations are more resilient and better able to withstand disturbances such as random fluctuations in birth rates (demographic stochasticity), and variation in rainfall and/or temperatures (environmental stochasticity).

Redundancy is defined as ensuring a sufficient number of populations to provide a margin of safety to reduce the risk of losing a species or certain representation (variation) within a species due to catastrophic events or other threats. Redundancy is essential for long-term viability (Shaffer and Stein 2000, pp. 307, 309–310; Groves *et al.* 2002, p. 506). This provides a margin of safety for a species to withstand catastrophic events (Service and NOAA 2011, p. 76994) by decreasing the chance of any one event affecting the entire species. Redundancy is about spreading risk and can be measured through the duplication and distribution of resilient populations across the range of the species.

Representation is defined as conserving ''some of everything'' with regard to genetic and ecological diversity to allow for future adaptation and maintenance of evolutionary potential. Representation and the adaptive capabilities (Service and NOAA 2011, p. 76994) of the Bone Cave harvestman are also important for long-term viability. Because a species' genetic makeup is shaped through natural selection by the environments it has experienced (Shaffer and Stein 2000, p. 308), populations should be protected in the array of different environments in which the invertebrate species occur as a strategy to ensure genetic representation, adaptive capability, and conservation of the species. Generally, the more representation, or diversity, the species has, the more it is capable of adapting to changes (natural or human caused) in its environment.

The recovery plan for the Bone Cave harvestman (Service 1994, pp. 86–88) identifies criteria for reclassification (from endangered to threatened), but does not include delisting criteria because we were uncertain about prospects for recovery and delisting of the species. These recovery criteria are a way of measuring our progress toward recovery. The recovery plan identifies two criteria for reclassifying the species from endangered to threatened:

(1) Three karst fauna areas (if at least three exist) within each karst fauna region in its range are protected in perpetuity. If fewer than three karst fauna areas exist within a given karst fauna region, then all karst fauna areas within that region should be protected.

(2) Criterion (1) has been maintained for at least 5 consecutive years with assurances that these areas will remain protected in perpetuity.

There are six karst fauna regions in Travis and Williamson Counties that are known to contain the Bone Cave harvestman (Service 1994, p. 33): North Williamson, Georgetown, McNeil/Round Rock, Cedar Park, Jollyville Plateau, and Central Austin. These regions are used as a way to facilitate conservation of representation and redundancy (as defined above) throughout the species' range.

For the purposes of the recovery plan, a karst fauna area ''is an area known to

support one or more locations of a listed species and is distinct in that it acts as a system that is separated from other karst fauna areas by geologic and hydrologic features and/or processes that create barriers to the movement of water, contaminants, and troglobitic fauna'' that live their entire lives underground (Service 1994, p. 76). Karst fauna areas should be far enough apart so that if a catastrophic event (for example, contamination of the water supply, flooding, disease) were to destroy one of the areas, that event would not likely destroy any other area occupied by that species (Service 1994, p. 76).

To be considered ''protected,'' a karst fauna area must be sufficiently large to maintain the integrity of the karst ecosystem on which the species depends (Service 1994, p. 87). In addition, these areas must also provide protection from threats such as red imported fire ants, habitat destruction, and contaminants.

The overall recovery strategy for the Bone Cave harvestman includes the perpetual protection and management of an adequate quantity and quality of habitat (three karst fauna areas in each karst fauna regions) that spans the species' geographic range and provides a high probability of the species' recovery and survival over the long term. Adequate quality (as discussed below) and quantity of habitat refers to both size and number of preserved karst fauna areas that are sufficient for supporting the karst invertebrates and the ecosystems upon which they depend (Service 2011, p. 16). The recovery plan criteria call for three karst fauna areas (preserves) in each karst fauna region. The size of karst fauna area preserves should be large enough to ensure resiliency as discussed above and to protect the environmental integrity of the karst ecosystems upon which the species depends. The number of karst fauna area preserves called for in the recovery criteria provides redundancy for the species. A minimal level of redundancy is essential to provide a margin of safety for the species to reduce the risk of losing the species or representation (variation) within the species from catastrophic events or other threats (Shaffer and Stein 2000 pp. 307, 309–310, Groves *et al.* 2002, p. 506). The Bone Cave harvestman has significant geographic variability across its range, and loss of a significant number of locations in part of its range could result in loss of genetic and ecological diversity. The conservation of multiple karst fauna area preserves across the Bone Cave harvestman's range should provide representation of the breadth of its genetic and ecological diversity to conserve its adaptive capabilities (Schaffer and Stein 2000, p. 308).

Adequate quality of habitat refers to (1) the condition and configuration of preserved lands with respect to the known localities for the species and (2) the ability of the species' needs to be met to sustain viable populations. Due to the uncertainty in determining population viability of the Bone Cave harvestman, the design of preserves for its protection should be based on estimates and assumptions that favor a high probability for recovery of this species and the ecosystems upon which it depends as discussed below.

The Endangered Karst Invertebrates Recovery Plan for Travis and Williamson Counties (Service 1994) calls for protecting karst fauna areas sufficiently large to maintain the integrity of the karst ecosystem on which the species depends. This focus on the ecosystem is consistent with the purpose of the Act, which includes ''to provide a means whereby the ecosystem upon which endangered species and threatened species depend may be conserved.'' Therefore, we recommend designing karst fauna area preserves to protect occupied karst feature(s) and associated mesocaverns (humanly impassable voids). For further guidance on how to provide for adequate quantity and quality of habitat at specific invertebrate locations, we have developed and refer to our Karst Preserve Design Recommendations (Service 2012).

According to our preserve design guidelines (Service 2012, p. 3–5), karst fauna area preserves should include the following: (1) Surface and subsurface drainage basins of at least one occupied cave or karst feature; (2) a minimum of 16 to 40 hectares (ha) (40 to 100 acres (ac)) of contiguous, unfragmented, undisturbed land to maintain native plant and animal communities around the feature and protect the subsurface karst community; (3) 105-meter (m) (345-feet (ft)) radius undisturbed area from each cave footprint for cave cricket foraging (cave crickets are an important source of nutrient input to the karst ecosystem) and to minimize deleterious edge effects; and (4) preserves should be free of pipelines, storage tanks, or other facilities (for example, water retention ponds) that could cause contamination.

In addition, due to the uncertainty in determining population viability and habitat requirements of the Bone Cave harvestman, the design of preserves for its protection should be based on estimates and assumptions that favor a high probability for recovery of the species and the ecosystems upon which it depends. This method follows a precautionary approach, which provides guidance to avert irreversible risk when facing uncertainty (Service 2012, p. A–1). The best available scientific information indicates that this species cannot be reintroduced into existing habitat. Life-history characteristics of this species indicate that it requires stable temperature and humidity (Barr 1968, p. 47, Mitchell 1971, p. 250) and suggest that this species cannot be reintroduced because it cannot withstand surface climatic conditions.

According to anecdotal reports provided to our field office, limited efforts to maintain karst invertebrates in a lab setting have been unsuccessful. Additionally, captive propagation techniques have not been developed for karst invertebrates and may be challenging to develop because of their specific adaptations to subterranean environment. Further, the sample size that would likely be needed to reintroduce a population into a new location cannot be obtained from existing populations due to the cryptic nature of this species and the fact that often only a few individuals are observed per cave survey. Therefore, an attempt to re-establish a population after it has been extirpated is not feasible at this time. In addition, if a preserve is later found to be insufficient to support the species due to surrounding developments being either too close or too dense, the potential for adequately conserving the site is lost.

Because the Bone Cave harvestman has a relatively long life span and low requirements for food, a decline in population size or even the complete extirpation of the population due to the influence of development or other threats may take years or even decades. Observations of this species over several years on a preserve that is too small for perpetual species preservation may not allow detection of declines that are actually occurring. If these observations are used as evidence that a preserve size was adequate, then the potential for long-term preservation of the species may be lost due to irreversible development surrounding the preserve. Therefore, preserve sizes should be established with caution and be large enough to account for the uncertainty in area requirements for a population.

According to the petition there are now more known occupied locations identified; there were 6 confirmed caves at listing, 60 confirmed caves at the time the recovery plan was drafted, and 168 confirmed caves in 2009 when the 5-year status review was completed (53 FR 36029, Service 1994, 2009). The

petition also states that more locations are likely to be found. We acknowledge there are more known locations since the time those documents were completed and the increase is likely an increase in our knowledge, not a true increase in the number of populations or range; however, species are listed under the Act based on threats and not just the number of sites or size of the range.

In addition, the petition states that 94 karst preserve areas are currently providing significant conservation. However, many of the existing protected areas referenced in the petition are too small to meet our preserve design recommendations. As part of the 2009 5-year status review of the Bone Cave harvestman, we reviewed the status of all of the known locations of the harvestman (including 83 of the 94 mentioned in the petition) to assess whether the criteria from the recovery plan to reclassify the species from endangered to threatened had been met for the Bone Cave harvestman. We considered the habitat size and condition to evaluate whether the locations could meet the preserve design recommendations (a reflection of the potential to support a resilient population) and then also looked at whether legally binding mechanisms were in place to provide protection of these sites over the long term (in perpetuity).

Of the locations known at the time of the 5-year review, 21 areas appeared to have the ability to meet the preserve design criteria. Our status review refers to 21 areas, while the petition indicates that the status review considered 28 sites. This discrepancy is because the petition considers each individual cave location, while our status review considered closely located caves to be part of the same karst fauna area. Of these 21 areas, 1 is no longer confirmed to have the species (Barker Ranch Cave No. 1), and 5 are now protected karst fauna areas (Priscilla's Well, Twin Springs, Cobbs Cavern, Karankawa, and Tooth Cave).

In addition, at most of the remaining locations (of the 21 areas) we are lacking information to confirm that they meet the preserve design criteria (such as surface and subsurface drainage basins, tract acreage, exact locations of the cave, and management activities to protect against threats, such as red imported fire ants). Also, many of these areas do not have a legally binding mechanism that ensures perpetual protection and management. Hence, we are unsure whether those areas have adequate undeveloped acreage, management, or protection mechanisms to ensure the long-term protection and survival of the Bone Cave harvestman.

Of the five protected karst fauna areas that meet preserve design criteria, four occur in the North Williamson County Karst Fauna Region and one occurs in the Jollyville Plateau Karst Fauna Region. However, this species occurs in six karst fauna regions, and four of these have no protected karst fauna areas that are confirmed to meet preserve design recommendations. Therefore, the best available information indicates that the criteria for reclassification from endangered to threatened for this species have not been met, nor has adequate representation and redundancy (three karst fauna areas in each karst fauna region) been protected throughout the species' range, leaving the species vulnerable to existing threats including habitat destruction.

The petition asserts that four additional locations are known since the time of the 5-year review. However, the petition does not provide adequate information that would support whether these four additional locations are in a condition to meet preserve design recommendations. Based on information in our files, we are aware of one additional cave since the 5-year review that may meet preserve design recommendations in the North Williamson Karst Fauna Region; however, it is privately owned, and we are unsure about the property acreage and if the site receives any type of protection or management. Regardless, the amount of protected karst fauna area still falls short of the criteria for reclassification from endangered to threatened.

Further, we reviewed 83 of the 94 caves identified in the petition as receiving some level of protection in the 5-year review. Two of the caves that we did not review (Cobbs Cavern and Whitney West Cave) are now in confirmed karst fauna areas mentioned above (Cobbs Cavern and Twin Springs), one (Pond Party Pit) is in the Beard Ranch Cave area discussed in the 5-year review, and we have no locality information or taxonomic verifications for the remaining caves and this information was not provided in the petition.

The petition also asserts that threats to the species are not as severe as originally thought. We evaluate that information, below, in respect to the five listing factors.

Factor A: The present or threatened destruction, modification, or curtailment of the species' habitat or range. In the 1988 listing rule (53 FR 36029), we stated that the primary threat to the Bone Cave harvestman was the potential loss of habitat due to development activities, which could result in filling in or collapsing of caves; alteration of drainage patterns; increase in flow of sediment, pesticides, fertilizers, and urban run-off into caves; and increase in human visitation and vandalism.

We also considered additional information on threats to the species when we developed the recovery plan for the species (Service 1994, pp. 59–65) and when we conducted the 5-year status review of the species (Service 2009, p. 2), in which we concluded that no change in the species' status (that is, reclassification to threatened or delisting) was warranted. We also reviewed available threat information in our files and in a 1993 petition when we made our negative 90-day finding on that petition to de-list (59 FR 11755).

The current petition asserts that ''Development activities on the surface may not result in the significant loss or degradation of habitat for *T. reyesi* as originally thought'' and suggests that evidence of this is the species persistence in caves surrounded by developed areas. Examples given in the petition are Inner Space Caverns, Sun City caves, Weldon Cave, Three-Mile Cave, and Four-Mile Cave. However, the observation of the species in these locations does not mean their populations at these locations are thriving or can withstand the long-term impacts from development activities that are expected to occur to karst invertebrate populations in developed areas as discussed in the listing rule, recovery plan, and 5-year status review for the Bone Cave harvestman.

Bone Cave harvestman populations may be declining or threatened even though they are still observed at a specific site. Information adequate to detect population trends for this species is not readily available and was not provided in the petition. This species has life-history strategies that include characteristics such as low metabolic and reproductive rates, long life spans, and inherently low sample sizes, which make it difficult to detect population response to possible impacts (Poulson and White 1969, p. 977, Howarth 1983, p. 374). We indicated in the 1994 90-day petition finding (59 FR 11755) that more time was needed to detect if the species was declining; however, while more time has passed, we are still lacking adequate data to conduct a trend analysis at most locations, given that it can take decades to detect population trends due to small sample sizes, the difficulty surveying for the species, and their long life spans.

In addition, some of the threats from development are due to the increased probability of chance events occurring in the future, such as a contaminant event like a pipeline leak, which exists because more contamination sources are in the vicinity of species' locations due to development.

The petition states that several Sun City caves are examples of areas where the species can persist in developed areas. However, the petition failed to provide data adequate to assess trends in the karst invertebrate populations since the development occurred. In addition, we worked with the Sun City developers when they designed the project to develop strategies that we believed at the time would avoid or minimize the possibility of ''take'' to listed karst species. While we now believe that most of the Sun City cave preserves are too small to meet our preserve design recommendations for recovery and long-term survival (Service 2012), we expect that the strategies and measures put in place likely have reduced the rate of impacts to the species.

The commercial cave known as Inner Space Caverns is another example the petition provided where the Bone Cave harvestman continues to persist in a developed area. Although the Bone Cave harvestman may be present at Inner Space Caverns, this does not ensure their populations are robust and secure; they may still be declining, and are at risk due to competition with surface-dwelling invertebrates and other threats associated with development such as the potential for contamination. This cave has an overgrowth of blue-green algae growing near cave lights where the petition states that this species has been observed. This type of algae is known as ''lampenflora'' and favors surface-dwelling invertebrate species that can out-compete karst invertebrate species (Mulec and Kosi 2009, p. 109, Culver 1986, p. 438), such as the Bone Cave harvestman. The petition failed to provide any data adequate to assess trends in the karst invertebrate population in relation to the time (duration and frequency) that they have been exposed to the artificial lighting. Additionally, part of the cave footprint occurs under a major interstate highway and train tracks, which both present a threat of a contaminant spill that could impact the species in the future.

Weldon Cave was another example in the petition of a cave occupied by the Bone Cave harvestman within a developed area. Based on the best available information in our files this cave is surrounded by undeveloped open space. Other than a small portion of the subsurface drainage basin potentially being impacted by a school campus, this cave appears to meet our preserve design recommendations but is not within a developed area, as asserted in the petition. Three-Mile Cave and Four-Mile Cave were also provided in the petition as examples of developed caves wherein the Bone Cave harvestman is known to occur. According to the petition, surveys conducted by SWCA in 2008 and 2009 documented the Bone Cave harvestman at these locations. However, detailed survey data were not provided by the petitioners and were not in the SWCA 2009 ''Annual Report of Activities Involving Endangered Karst Invertebrates under Threatened and Endangered Species Permit TE800611–2.''

The petition also states that, since the Bone Cave harvestman uses mesocaverns, it is protected from surface development activities because mesocaverns are ''geologically protected.'' We are unclear why the petition contends that mesocaverns are protected because mesocaverns are subject to rapid permeation of surface water (Cowan *et al.* 2007, p. 160), and karst landscapes (including mesocaverns) are particularly susceptible to groundwater contamination because water penetrates rapidly through bedrock conduits providing little or no filtration (White 1988, p. 149).

One of the major threats to the Bone Cave harvestman is habitat loss due to increasing urbanization. The Bone Cave harvestman is a troglobite, meaning it lives its entire life underground. Karst ecosystems are heavily reliant on surface plant and animal communities for nutrient input.

Caves in central Texas that are occupied by federally listed karst invertebrates, such as the Bone Cave harvestman, receive energy (or nutrients) primarily from (1) detritus (decomposing organic matter) that falls or is washed into the caves and (2) energy brought into the caves by cave crickets (*Ceuthophilus* spp.) (Barr 1968, p. 48; Reddell 1993, p. 2; Lavoie *et al.* 2007, p. 114; Taylor 2003, p. 3, 2004, p. 2, 2005, p. 97), which are found in most Texas caves (Reddell 1966, p. 33). Cave crickets forage widely in the surface habitat surrounding the cave. Karst invertebrates feed on the cave cricket eggs (Mitchell 1971, p. 251), feces (Barr 1968, pp. 51–53, Poulson *et al.* 1995, p. 226), and directly on the crickets themselves (Elliott 1994, p. 15).

Development within urbanized areas can destroy or alter the surface plant and animal communities on which karst invertebrates depend. As development increases within the cave crickets' foraging area, there may be dramatic shifts in the available food supply within the cave (Taylor *et al.* 2007, p. 7). The leaf litter and other decomposing material that make up most of the detritus from the surface plant and animal community may also be reduced or altered, resulting in a reduction of nutrient and energy flow into the cave. A study by Taylor *et al.* (2007) compared caves in urbanized areas that were impacted by development to those in natural areas and found that, even though a small area within a largely urbanized ecosystem may support a cave community where karst invertebrates are occasionally seen, these populations are significantly lower than those found in caves in more natural, less developed ecosystems, most likely as a result of reduced nutrient input. Another study at Lakeline Cave in Travis County, Texas, was conducted in association with the issuance of a habitat conservation plan and accompanying section 10(a)(1)(B) permit issued for Lakeline Mall. That study is based on data collected from 1992 through 2011, and it documented a significant decline during that 20-year timeframe in another endangered karst invertebrate, *Rhadine persephone,* and cave crickets as development increased (ZARA 2012, pp. 8, 10, 12). Further, at Lakeline Mall Cave, no more than three Bone Cave harvestmen have been observed during any single survey (ZARA 2012, p. 11). Also, no Bone Cave harvestmen were seen during 6 years (1993, 1999, 2001, 2006, 2009, and 2010) and 12 surveys in Lakeline Mall Cave (ZARA 2012, p. 11).

Available information in our files supports our projection in the 1988 listing rule that development and human population would continue to increase within the range of the species. The population of the City of Austin grew from 251,808 people in 1970 to 735,088 people in 2007 (City of Austin 2007). This represents a 192-percent increase over the 37-year period. Population projections from the Texas State Data Center (2012, pp. 496–497), estimate that Travis County will increase 94 percent in population from 1,024,266 in 2010, to 1,990,820 in 2050. The Texas State Data Center also estimates an increase in human population in Williamson County from 422,679 in 2010, to 2,015,294 in 2050 representing a 377-percent increase over a 40-year timeframe. All human population projections from the Texas State Data Center presented here are under a high-growth scenario, which

assumes that migration rates from 2000 to 2010 will continue through 2050 (Texas State Data Center and the Office of the State Demographer 2012, p. 9). Urbanization and human population growth and development were identified as a threat in the original 1988 listing rule and continue to represent a threat to the species.

Factor B: Overutilization for commercial, recreational, scientific, or educational purposes. In the 1988 listing rule for the Bone Cave harvestman, we did not identify any threats under this factor. Likewise, the petition and our review of the information in our files did not identify any threats under this factor.

Factor C: Disease or predation. In the 1988 listing rule, we stated that increased human population increases the threat of predation by and competition with exotic (non-native) and native surface-dwelling species, such as sow bugs, cockroaches, and red imported fire ants. The petition states that ''Recent studies suggest that fire ants may not present as significant or as lasting of a threat to the species as originally believed.'' The information cited regarding red imported fire ants is identified in the petition as an article by Porter and Savignano (1990), which we previously considered in our finding on the 1993 petition, and another study by Morrison (2002). The petition states that ''a subsequent study by Morrison in 2002 revisited the Porter and Savignano (1990) study area 12 years later and replicated their study.

Morrison (2002, pp. 2341, 2343–2344) found that arthropod communities had rebounded to pre-RIFA [red imported fire ant]-invasion levels and that all measures of native ant and other arthropod species' diversity had returned to pre-invasion levels. Red imported fire ants were still the most abundant ant species, but not nearly as abundant as during the initial red imported fire ants infestation. He concluded that the impacts to arthropod communities by red imported fire ants might be greatest during and shortly after the initial invasion, but long-term impacts are likely not as significant as once believed. However, we note that Morrison (2002, p. 2342) also states that ''it is quite likely that red imported fire ants did contribute directly or indirectly to the disappearance or reduction in numbers of species'' and that their study ''should not be interpreted as an indication that detrimental effects of invasive ants will simply disappear with time.'' In addition, this is not ''new information'' as we have already reviewed these articles and considered the information they provided in the Bexar County Karst Invertebrates Recovery Plan (Service 2011, p. 12) and in our Karst Preserve Management and Monitoring Recommendations (Service 2014, p. 3), which is applicable here as all central Texas endangered karst invertebrates have similar life-history characteristics, and one of the Bexar County invertebrates is in the same genus (*Texella*) as the Bone Cave harvestman. In addition, red imported fire ants have been found within and near many caves in central Texas and have been observed feeding on dead troglobites, cave crickets, and other species within caves (Elliott 1992, p. 13, 1994, p. 15, 2000, pp. 668, 768; Reddell 1993, p. 10; Taylor *et al.* 2003, p. 3).

Factor D: The inadequacy of existing regulatory mechanisms. The 1988 listing rule states that ''there are currently no laws that protect any of these species or that indirectly address protection of their habitat.''

While the petition did discuss some new ordinances that appear to have been put in place since the time of listing, we do not have enough information to indicate whether or not these State and local ordinances provide enough protection from all threats to the Bone Cave harvestman.

The petition states that ''the regulatory landscape includes a number of measures contributing to the conservation of the species outside of the protections afforded by the Endangered Species Act of 1973, as amended.'' For example, they say that protections offered though the City of Austin are adequate to protect the species in Austin, Texas. In the course of our work, we have reviewed these regulations and understand that most caves that are defined by the City of Austin's Environmental Criteria Manual as a cave are provided a 46- to 91-m (150- to 300-ft) set-back area (City of Austin 2014, p. 13–3). However, a 46-m (150-ft) or 91-m (300-ft) set-back is not adequate to meet our preserve design criteria, does not protect the cave cricket foraging area, and potentially does not include the surface and subsurface drainage basins. Further, it is not applicable across the range of the Bone Cave harvestman because the species occurs in Travis and Williamson Counties and the City of Austin does not cover all of those counties.

The petition states that the City of Georgetown Water Quality Management Plan for the Georgetown salamander will offer protection to the Bone Cave harvestman. They state that this plan encourages the use of best management practices to protect water quality at Georgetown salamander locations. However, there are few Bone Cave harvestman locations that occur near Georgetown salamander locations, so any protection offered to the harvestman would be limited. Further, it is not clear from the petition whether this mechanism is voluntary or if it is regulatory or if it is currently in effect. In addition, the petition did not provide enough detail for us to evaluate all benefits this plan would provide to the Bone Cave harvestman, and it appears that participation in this plan is at least in part voluntary.

The petition states that the Texas Commission on Environmental Quality (TCEQ) Edwards Rules provide protection to recharge features on the Edwards Plateau and that this provides protection from pollution to the Bone Cave harvestman. In a discussion of Factor D in the Bexar County Karst Invertebrates Recovery Plan (Service 2011, p. 13), we state that ''the TCEQ water quality regulations do not provide much protection to the species' habitat (see 65 FR 81419–81433 for more information). For example, while some TCEQ practices provide protection from water quality impacts, others, such as sealing cave entrances for water quality reasons, can harm karst invertebrates.'' Sealing cave entrances can be harmful by blocking off water (leading to drying) and nutrient input to the karst invertebrate habitat. In addition, not all of the caves and mesocaverns that the Bone Cave harvestman occurs in are considered recharge features and, therefore, would not receive some of the water quality protection measures. Also, not all locations of the Bone Cave harvestman are under the jurisdiction of the Edwards Rules.

Factor E: Other natural or manmade factors affecting the continued existence of the species. In the 1988 listing rule, we stated that this species is extremely vulnerable to losses because of its severely limited range and because of its naturally limited ability to colonize new habitats. We also stated that the very small size of the species habitat units and the fragile nature of cave ecosystems make them vulnerable to even isolated acts of vandalism. The petition states, ''Inner Space Cavern demonstrates that the species can persist in caves with frequent human visitation and may be more tolerant of related habitat modification than originally believed.'' They also provide Three-Mile Cave and Four-Mile Cave as examples of caves that have experienced human use yet the species persists. The petition contends that, since the Bone Cave harvestman exists in Inner Space Caverns, human visitation is not a threat. The petition also states that Three-mile and Four-mile Cave had

graffiti from the 1890s, 1920s, and 1950s. Yet, no detailed information was provided to demonstrate if these caves experienced continued human use. The petition also indicates that Four-Mile Cave was inaccessible to humans prior to 2009 due to boulders blocking the entrance. In addition, the petition provided no trend analysis for these caves. As stated earlier, the observation of the species in these locations does not mean the populations at these locations have not been impacted (in a way that is short of extirpation) or can withstand the long-term impacts that are expected to occur to karst invertebrate populations in developed areas or from human visitation.

In the species 5-year status review (Service 2009, p. 18) we said, ''Although climate change was not identified as a threat to *T. reyesi* in the original listing document or in the recovery plan, the species' dependence on stable temperatures and humidity levels opens the possibility of climatic change impacting this species. Therefore, while it appears reasonable to assume that *T. reyesi* may be affected, we lack sufficient certainty to know how climate change will affect this species.''

The petitioners state that ''the use of small voids or 'mesocaverns' within the geologic formations known to support occupied caves mitigates the potential threat of climate change.'' We acknowledge that mesocaverns may provide some protection from fluctuations in temperature and humidity that may be induced by climate change. However, the presence of mesocaverns alone will likely not be sufficient to ameliorate all of the effects that climate change may pose to this species. Karst invertebrates depend on stable temperatures and high humidity (Barr 1968, p. 47, Mitchell 1971, p. 250). The temperatures in caves are typically the average annual temperature of the surface habitat and vary much less than the surface environment (Howarth 1983, p. 372, Dunlap 1995, p. 76). If average surface temperatures increase, this could result in increased in-cave temperatures, which could affect the Bone Cave harvestman.

Increased and/or more severe storms as well as prolonged periods of high temperatures and drought between rainfall events associated with predicted climate change effects may also impact the cave environment. Changes in rainfall regimes may affect the harvestman in several ways, including directly either through flooding or indirectly by modifying their habitat or nutrient availability. Changes in rainfall regimes could (1) alter the moisture levels within the caves leaving them drier between floods, which could lead to desiccation of the Bone Cave harvestman and (2) affect the amount and timing of nutrients washed into a cave, potentially resulting in longer periods between nutrient input. These changes to drier and less suitable conditions in the caves will likely cause the Bone Cave harvestman to retreat farther into mesocaverns and away from nutrients that are thought to be located in larger cave passages (Howarth 1987, pp. 5–7), causing individuals to spend more energy trying to acquire nutrients in an already stressed environment. In addition, caves in arid regions have been shown to have smaller invertebrate populations and diversity due to less moisture and nutrient availability (George Veni, National Cave and Karst Research Institute, pers. comm. 2010). Since the Bone Cave harvestman is also sensitive to these habitat parameters, it is reasonable to predict that climate change could affect its populations in a similar manner despite the presence of mesocaverns.

Further, stochastic (random) events from either environmental factors (for example, severe weather) or demographic factors (which come from the chance events of birth and death of individuals) exacerbate threats to the species because of its small population size (Melbourne and Hastings 2008, p. 100). The risk of extinction for any species is known to be highly inversely correlated with population size (Pimm *et al.* 1988, pp. 774–775, O'Grady *et al.* 2004, pp. 516, 518). In other words, the smaller the population the greater the overall risk of extinction. Therefore, threats to the Bone Cave harvestman are exacerbated by its small population size, which makes it more vulnerable to existing threats.

Finding

We have reviewed the petition and also evaluated readily available, related information in our files. The petitioners have based their assessment that the species can thrive in developed areas on information that we have already reviewed (except in 4 caves discovered since the 5-year status review and 7 for which we lack locality information or taxonomic verifications) while working on previous documents (Service 2009, 2012) or on observations that lack a large enough sample size to produce population trend information for the Bone Cave harvestman. The petition provided no trend analysis to indicate that this species can withstand the threats associated with development or climate change over the long term. Based on our review and evaluation, we find that the petition does not present substantial scientific or commercial information indicating that delisting of the Bone Cave harvestman may be warranted due to recovery, extinction, or error in the original scientific data at the time the species was classified or in our interpretation of the data. However, much progress has been made toward recovery in the North Williamson and Jollyville Plateau Karst Fauna Regions. We encourage interested parties to continue to gather data and implement conservation actions across the range of the Bone Cave harvestman that will further assist with the conservation of this species. If you wish to provide information regarding the Bone Cave harvestman, you may submit your information or materials to the Field Supervisor, Austin Ecological Services Field Office (see **ADDRESSES**) at any time.

References Cited

A complete list of references cited is available on the Internet at *http://www.regulations.gov* and upon request from the Austin Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this notice are staff members of the Austin Ecological Services Office.

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: May 21, 2015.

Gary Frazer,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2015–13136 Filed 5–29–15; 8:45 am]

BILLING CODE 4310–55–P

Notices

Federal Register
Vol. 80, No. 104
Monday, June 1, 2015

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2014–0007]

Monsanto Co.; Availability of Preliminary Plant Pest Risk Assessment and Draft Environmental Assessment of Maize Genetically Engineered for Protection Against Corn Rootworm and Resistance to Glyphosate

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service is making available for public comment a preliminary plant pest risk assessment and draft environmental assessment for maize designated as event MON 87411, which has been genetically engineered for protection against corn rootworm and resistance to the herbicide glyphosate.

DATES: We will consider all comments that we receive on or before July 1, 2015.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0007.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2014–0007, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents for this petition and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0007* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

Supporting documents for this petition are also available on the APHIS Web site at *http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml* under APHIS Petition Number 13–290–01p.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 851–3954, email: *john.t.turner@aphis.usda.gov.* To obtain copies of the petition, contact Ms. Cindy Eck at (301) 851–3892, email: *cynthia.a.eck@aphis.usda.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, ''Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests,'' regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered ''regulated articles.''

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. APHIS received a petition (APHIS Petition Number 13–290–01p) from the Monsanto Company (Monsanto) of St. Louis, MO, seeking a determination of nonregulated status of maize (*Zea mays*) designated as event MON 87411, which has been genetically engineered for protection against corn rootworm and resistance to the herbicide glyphosate. The Monsanto petition states that information collected during field trials and laboratory analyses indicates that MON 87411 maize is not likely to be a plant pest and therefore should not be a regulated article under APHIS' regulations in 7 CFR part 340.

According to our process [1] for soliciting public comment when considering petitions for determinations of nonregulated status of GE organisms, APHIS accepts written comments regarding a petition once APHIS deems it complete. In a notice [2] published in the **Federal Register** on March 7, 2014 (79 FR 13035–13036, Docket No. APHIS–2014–0007), APHIS announced the availability of the Monsanto petition for public comment. APHIS solicited comments on the petition for 60 days ending on May 6, 2014, in order to help identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition. APHIS received 423 comments on the petition. Issues raised during the comment period include the contamination of conventional crop production, the potential for disruption of trade due to the presence of unwanted genetically engineered commodities in exports, the potential for negative impacts to plant fitness and the environment, and health concerns. APHIS has evaluated the issues raised during the comment period and, where appropriate, has provided a discussion of these issues in our draft environmental assessment (EA).

After public comments are received on a completed petition, APHIS evaluates those comments and then provides a second opportunity for public involvement in our decisionmaking process. According to our public review process (see footnote 1), the second opportunity for public involvement follows one of two approaches, as described below.

If APHIS decides, based on its review of the petition and its evaluation and analysis of comments received during the 60-day public comment period on the petition, that the petition involves a GE organism that raises no substantive new issues, APHIS will follow Approach 1 for public involvement.

[1] On March 6, 2012, APHIS published in the **Federal Register** (77 FR 13258–13260, Docket No. APHIS–2011–0129) a notice describing our public review process for soliciting public comments and information when considering petitions for determinations of nonregulated status for GE organisms. To view the notice, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129.*

[2] To view the notice, the petition, and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0007.*

Under Approach 1, APHIS announces in the **Federal Register** the availability of APHIS' preliminary regulatory determination along with its EA, preliminary finding of no significant impact (FONSI), and its plant pest risk assessment (PPRA) for a 30-day public review period. APHIS will evaluate any information received related to the petition and its supporting documents during the 30-day public review period.

If APHIS decides, based on its review of the petition and its evaluation and analysis of comments received during the 60-day public comment period on the petition, that the petition involves a GE organism that raises substantive new issues, APHIS will follow Approach 2. Under Approach 2, APHIS first solicits written comments from the public on a draft EA and preliminary PPRA for a 30-day comment period through the publication of a **Federal Register** notice. Then, after reviewing and evaluating the comments on the draft EA and preliminary PPRA and other information, APHIS will revise the PPRA as necessary and prepare a final EA and, based on the final EA, a National Environmental Policy Act (NEPA) decision document (either a FONSI or a notice of intent to prepare an environmental impact statement). For this petition, we are using Approach 2.

As part of our decisionmaking process regarding a GE organism's regulatory status, APHIS prepares a PPRA to assess the plant pest risk of the article. APHIS also prepares the appropriate environmental documentation—either an EA or an environmental impact statement—in accordance with NEPA, to provide the Agency and the public with a review and analysis of any potential environmental impacts that may result if the petition request is approved.

APHIS has prepared a preliminary PPRA and has concluded that maize designated as event MON 87411, which has been genetically engineered for protection against corn rootworm and resistance to the herbicide glyphosate, is unlikely to pose a plant pest risk. In section 403 of the Plant Protection Act, ''plant pest'' is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing.

APHIS has also prepared a draft EA in which we present two alternatives based on our analysis of data submitted by Monsanto, a review of other scientific data, field tests conducted under APHIS oversight, and comments received on the petition. APHIS is considering the following alternatives: (1) Take no action, *i.e.,* APHIS would not change the regulatory status of maize designated as event MON 87411, or (2) make a determination of nonregulated status of maize designated as event MON 87411.

The EA was prepared in accordance with (1) 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).

In accordance with our process for soliciting public input when considering petitions for determinations of nonregulated status for GE organisms, we are publishing this notice to inform the public that APHIS will accept written comments on our draft EA and our preliminary PPRA regarding the petition for a determination of nonregulated status from interested or affected persons for a period of 30 days from the date of this notice. Copies of the draft EA and the preliminary PPRA, as well as the previously published petition, are available as indicated under **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** above.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. After reviewing and evaluating the comments on the draft EA and the preliminary PPRA and other information, APHIS will revise the PPRA as necessary and prepare a final EA. Based on the final EA, APHIS will prepare a NEPA decision document (either a FONSI or a notice of intent to prepare an environmental impact statement). If a FONSI is reached, APHIS will furnish a response to the petitioner, either approving or denying the petition. APHIS will also publish a notice in the **Federal Register** announcing the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, FONSI, and our regulatory determination.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 22nd day of May 2015.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015–13164 Filed 5–29–15; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—USDA National Hunger Clearinghouse Database Forms FNS 543 and FNS 543–A

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This is a revision of a currently approved collection for the purpose of collecting information from organizations fighting hunger and poverty.

DATES: Written comments must be received on or before July 31, 2015.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to: Tony Craddock, Jr., Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 941, Alexandria, VA 22302. Comments may also be submitted via email to Tony Craddock, Jr. at *tony.craddock@fns.usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov* and follow the online instructions for submitting comments electronically. Comments will also be accepted through the

Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All written comments will be available for public inspection at the office of the Food and Nutrition Service located at 3101 Park Center Drive, Room 941, Alexandria, Virginia 22302 during regular business hours (8:30 a.m. to 5:00 p.m. Monday through Friday).

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Tony Craddock, Jr. at 703–605–0037.

SUPPLEMENTARY INFORMATION:

Title: USDA National Hunger Clearinghouse Database Forms.

Form Number: FNS–543 and FNS 543–A.

OMB Number: 0584–0474.

Expiration Date: 09/30/2015.

Type of Request: Revision of a currently approved information collection.

Abstract: Section 26 of the Richard B. Russell National School Lunch Act (42 U.S. C. 1769g) (the Act), which was added to the Act by section 123 of Public Law 103–448 on November 2, 1994, mandated that FNS enter into a contract with a non-governmental organization to establish and maintain an information clearinghouse (named ''USDA National Hunger Clearinghouse'' or ''Clearinghouse'') for groups that assist low-income individuals or communities regarding nutrition assistance programs or other assistance. Section 26(d) of this Act was amended again by Public Law 113–79 on February 7, 2014, to extend funding for the Clearinghouse through fiscal year 2015 for $250,000. FNS awarded this contract to the hunger advocacy organization New York City Coalition Against Hunger (NYCCAH) on October 1, 2014.

The Clearinghouse includes a database of non-governmental, grassroots organizations in the areas of hunger and nutrition, along with a mailing list to communicate with these organizations. These organizations enter their information into the database, and Clearinghouse staff use that information to provide the public with information about where they can get food assistance. The database form (FNS–543) will be completed online at *www.nhc.fns.usda.gov* and physical versions of the form can still be completed and emailed to *tony.craddock@fns.usda.gov.* State agencies use the FNS–543A form to voluntarily collect information about summer meal sites. The FNS–543A collects site name, location and operating details such as dates and times of the day that the site is in operation. FNS–543A is part of the information collection because summer meal site information is part of the National Hunger Clearinghouse.

Affected Public: Business or Other For-Profits, and Not For Profit (FNS 543) and State Agencies (FNS 543–A). Respondent group types for FNS–543 are identified as Food banks. Most of these groups are organizations providing nutrition assistance services to the public. Respondent groups identified for FNS–543A include all 55 State Agencies.

As of February 2015, there were 6,011 registered organizations in the National Hunger Clearinghouse. FNS estimates approximately 600 new business registrants annually. Each respondent is expected to only participate in one survey per registration.

Reporting Burden for FNS–543

Estimated Number of Respondents: 600.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Responses: 600.

Estimated Time per Response: 5 minutes (0.0833 hours).

Estimated Total Annual Burden on Respondents: 49.98 hours rounded up to 50 hours.

Reporting Burden for FNS–543–A.

Estimated Number of Respondents: 55.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Responses: 55.

Estimated Time per Response: 1.05 hours.

Estimated Total Annual Burden on Respondents: 57.75 hours rounded up to 58 hours.

The total reporting burden for this information collection is 108 total annual burden hours and 655 total annual responses.

See the table below for estimated total annual burden for each type of respondent and each FNS form.

FNS–543

Respondent	Estimated number of respondents	Responses annually per respondent	Total annual responses	Estimated average number of hours per response	Estimated total hours
Business Reporting Burden					
Food Banks	300	1	300	0.0833	24.99
Business and Other For Profit	100	1	100	0.0833	8.33
Not For Profit	200	1	200	0.0833	16.66
Total Reporting Burden	600		600		49.98

FNS–543A

Respondent	Estimated number of respondents	Responses annually per respondent	Total annual responses	Estimated average number of hours per response	Estimated total hours
State Agencies Reporting Burden					
State agencies	55	1	55	1.05	57.75

FNS–543A—Continued

Respondent	Estimated number of respondents	Responses annually per respondent	Total annual responses	Estimated average number of hours per response	Estimated total hours
Total Reporting Burden	55		55		57.75

Dated: May 19, 2015.

Jeffrey J. Tribiano,

Acting Administrator, Food and Nutrition Service.

Attached:

Appendix A: USDA National Hunger Clearinghouse Database Form FNS543 (paper)

Appendix B: USDA National Hunger Clearinghouse Database Form FNS543 (online)

Appendix C: USDA National Hunger Clearinghouse Database Form FNS543–A

BILLING CODE 3410–30–P

Appendix A: USDA National Hunger Clearinghouse Database Form FNS 543 (paper)

OMB Number 0584-0474
Expiration Date: XX/XX/XXXX

USDA NATIONAL HUNGER CLEARINGHOUSE DATABASE FORM

Facilitating the exchange of information, resources and ideas among organizations fighting hunger and poverty.

Public reporting burden for this collection of information is estimated to average five minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information including suggestions for reducing burden to: U.S. Department of Agriculture, Food and Nutrition services, Office of Research, Nutrition and Analysis, Room 1014, (0584-0474), Alexandria, VA 22302. Do not return completed form to this address.

The following information will be added to the USDA National Hunger Clearinghouse Database, an online resource that provides information about food assistance to the public. Please complete this form and return it to the New York City Coalition Against Hunger (NYCCAH)

Date: _____ Organization Name: _____

Physical Address _____

City: _____ State: _____ Zip Code: _____

Phone: _____ ext: _____ Fax: _____ Email: _____

Hours of Service: _____ Website: _____

Would you like to receive our monthly e-newsletter? ☐ Yes ☐ No

Organizational Information:

How would you classify your organization? (select all that apply)

☐ Advocacy ☐ Education Institution ☐ Labor
☐ Coalition ☐ Emergency Food Provider ☐ Religious
☐ Direct Services ☐ Funder

What is your organization's target population? (select all that apply)

☐ Families ☐ Immigrants ☐ Youth
☐ Homeless/Unemployed ☐ Senior Citizens ☐ Other _____

Where does your organization provide services?

☐ Business ☐ Extension Service ☐ Religious institution
☐ Child Care Center ☐ Farm ☐ School
☐ College University ☐ Health Care Facility ☐ Senior Citizen Center
☐ Community Center ☐ Home/Residence ☐ Shelter
☐ Correction Facility ☐ Organizational Offices ☐ Soup Kitchen/Food Pantry
☐ Detention Facility ☐ Public Housing

What area does your organization serve?

☐ County ☐ Regional ☐ Suburban
☐ National ☐ Rural ☐ Urban
☐ Neighborhood ☐ State

USDA National Hunger Clearinghouse - part of New York City Coalition Against Hunger's (NYCCAH) Grassroots Action Network
50 Broad Street, Suite 1520
New York, NY 10004
Tel: 212-825-0028
Fax: 212-825-0267
clearinghouse@nyccah.org

Agency Services
(Please Mark All That Apply)

Children Service:
- ☐ After School
- ☐ Day Care/Childcare
- ☐ Foster Care/Childcare
- ☐ Other _____

Counseling:
- ☐ Case Management
- ☐ Crisis Hotline
- ☐ Domestic Violence
- ☐ Drugs and Alcohol
- ☐ Family Support
- ☐ Individual
- ☐ Referral Services
- ☐ Sexual Assault
- ☐ Other _____

Education:
- ☐ ESL
- ☐ Head Start
- ☐ Nutrition Education
- ☐ Prison Re-entry Program
- ☐ Other _____

Food Assistance:
- ☐ Community Support Agriculture
- ☐ Farmer's Markets (EBT)
- ☐ Food Bank
- ☐ Food Delivery
- ☐ Food Pantry
- ☐ Kids Café
- ☐ Meals On Wheels
- ☐ Soup Kitchens
- ☐ Other _____

Government Programs:
- ☐ Child and Adult Care Food Program
- ☐ CSFP
- ☐ Earned Income Tax Credit
- ☐ Farmer's Market Nutrition Program
- ☐ FEMA/Disaster Relief
- ☐ Home Emergency Relief
- ☐ Senior Farmer's Market Nutrition Program
- ☐ SNAP
- ☐ Summer Food Service Program
- ☐ TANF
- ☐ TEFAP
- ☐ WIC
- ☐ Other _____

Health Care:
- ☐ Health Clinic
- ☐ Prescription Assistance
- ☐ Other _____

Homeless Services
- ☐ Drop In Center
- ☐ Emergency Shelter
- ☐ Halfway Home
- ☐ Transitional Housing
- ☐ Other _____

Housing:
- ☐ Appliances/Furniture
- ☐ Home Repairs
- ☐ Rent Subsidy
- ☐ Utilities Assistance
- ☐ Weatherization
- ☐ Other _____

Jobs:
- ☐ Career Counseling
- ☐ Job Placement
- ☐ Job Readiness
- ☐ Other _____

Other Services:
- ☐ Clothes
- ☐ Hunger Hotline
- ☐ Thrift Store

Do you do perform advocacy work? If so, please indicate what kind

Do you provide transportation services? ☐ Yes ☐ No

Do you accept food donations? ☐ Yes ☐ No

Do you provide seasonal services? (i.e. Christmas baskets) ☐ Yes ☐ No

Mission Statement: _____

_____

******Please write or attach a description of your organization's background and programs******

Contact Information

The following information is for internal use only. Please provide the contact information for the point of contact for the New York City Coalition Against Hunger to provide periodic updates of the organizational information above.

First Name: _____ Middle Initial: _____ Last Name: _____

Title: _____ Phone: _____ ext: _____

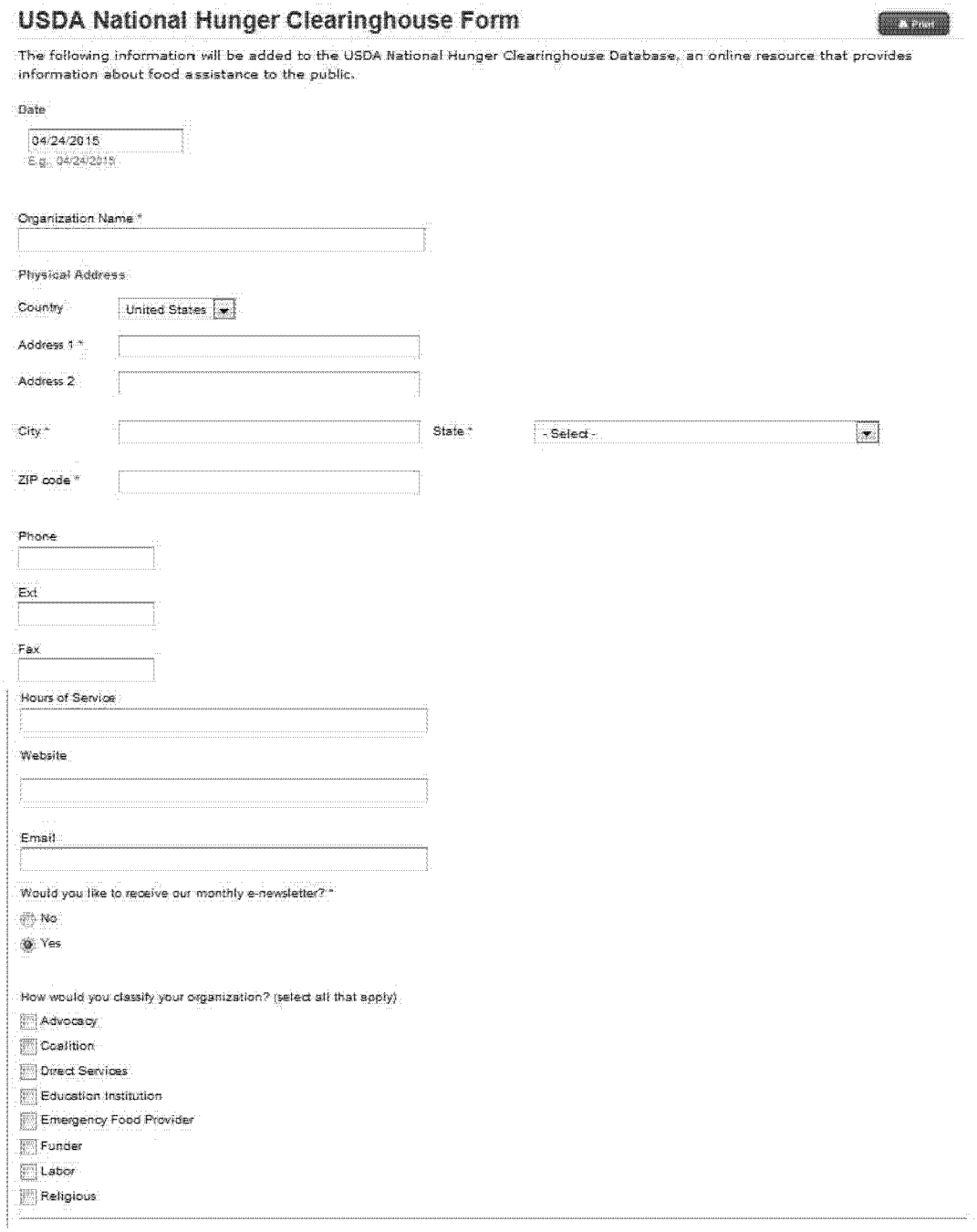
Mobile Phone _____ Fax: _____ Email: _____

Physical Address _____

City: _____ State: _____ Zip Code: _____

USDA National Hunger Clearinghouse - part of New York City Coalition Against Hunger's (NYCCAH) Grassroots Action Network
50 Broad Street, Suite 1520
New York, NY 10004
Tel: 212-825-0028
Fax: 212-825-0267
clearinghouse@nyccah.org

Appendix B: USDA National Hunger Clearinghouse Database Form FNS 543 (online)



USDA National Hunger Clearinghouse Form

Print

The following information will be added to the USDA National Hunger Clearinghouse Database, an online resource that provides information about food assistance to the public.

Date

04/24/2015

E.g., 04/24/2015

Organization Name *

Physical Address

Country United States

Address 1 *

Address 2

City * State * - Select -

ZIP code *

Phone

Ext

Fax

Hours of Service

Website

Email

Would you like to receive our monthly e-newsletter? *

No

Yes

How would you classify your organization? (select all that apply)

Advocacy

Coalition

Direct Services

Education Institution

Emergency Food Provider

Funder

Labor

Religious

What is your organization's target population? (select all that apply)

- [ ] Families
- [ ] Homeless/Unemployed
- [ ] Immigrants
- [ ] Senior Citizens
- [ ] Youth

Other

Where does your organization provide services? (select all that apply)

- [ ] Business
- [ ] Child Care Center
- [ ] College University
- [ ] Community Center
- [ ] Correction Facility
- [ ] Detention Facility
- [ ] Extension Service
- [ ] Farm
- [ ] Health Care Facility
- [ ] Home/Residence
- [ ] Microfinance
- [ ] Networking
- [ ] Organizational Offices
- [ ] Public Housing
- [ ] Religious Institution
- [ ] School
- [ ] Senior Citizen Center
- [ ] Shelter
- [ ] Soup Kitchen/Food Pantry

What area does your organization serve? (select all that apply)

- [ ] County
- [ ] National
- [ ] Neighborhood
- [ ] Regional
- [ ] Rural
- [ ] State
- [ ] Suburban
- [ ] Urban

Children Service: (select all that apply)

- [ ] After School
- [ ] Day Care/Childcare
- [ ] Foster Care/Childcare

Other

Counseling: (select all that apply)

- [ ] Case Management
- [ ] Crisis Hotline
- [ ] Domestic Violence
- [ ] Drugs and Alcohol
- [ ] Family Support
- [ ] Individual
- [ ] Referral Services
- [ ] Sexual Assault

Other

Education: (select all that apply)

- [ ] ESL
- [ ] Head Start
- [ ] Nutrition Education
- [ ] Prison Re-entry Program

Other

Food Assistance: (select all that apply)

- [ ] Community Support Agriculture
- [ ] Farmer's Markets (EBT)
- [ ] Food Bank
- [ ] Food Delivery
- [ ] Food Pantry
- [ ] Kids Cafe
- [ ] Meals On Wheels
- [ ] Soup Kitchens

Other

Government Programs: (select all that apply)

- [ ] Child and Adult Care Food Program
- [ ] CSFP
- [ ] Earned Income Tax Credit
- [ ] Farmer's Market Nutrition Program
- [ ] FEMA/Disaster Relief
- [ ] Home Emergency Relief
- [ ] Senior Farmers Mkt Nutrition
- [ ] SNAP (formerly known as "Food Stamps")
- [ ] Summer Food Service Program
- [ ] TANF
- [ ] TEFAP
- [ ] WIC

Other

Health Care: (select all that apply)

- [ ] Health Clinic
- [ ] Prescription Assistance

Other

Homeless Services: (select all that apply)

- [ ] Drop In Center
- [ ] Emergency Shelter
- [ ] Halfway Home
- [ ] Transitional Housing

Other

Housing: (select all that apply)

- [ ] Appliances/Furniture
- [ ] Home Repairs
- [ ] Rent Subsidy
- [ ] Utilities Assistance
- [ ] Weatherization

Other

Jobs: (select all that apply)

- [ ] Career Counseling
- [ ] Job Placement
- [ ] Job Readiness

Other

Other Services: (select all that apply)

- [ ] Clothes
- [ ] Hunger Hotline
- [ ] Thrift Store

Do you do advocacy work? If so, please indicate what kind

maximum 255 characters

Do you provide transportation services? *

- (•) No
- ( ) Yes

Do you accept food donations? *

- (•) No
- ( ) Yes

Do you provide seasonal services? (i.e. Christmas baskets) *

- (•) No
- ( ) Yes

Mission Statement

▾ Contact Information

The following information is for internal use only. Please provide the contact information for your organization's point of contact. The New York City Coalition Against Hunger (NYCCAH) will provide periodic updates on food assistance resources.

First Name *

Middle Initial

Last Name *

Title

Phone *

Ext

Mobile Phone

Fax

Email *

▾ Contact's Address

Country United States

Address 1 *

Address 2

City * State * - Select -

ZIP code *

Appendix C: USDA National Hunger Clearinghouse Database Form FNS 543-A

FNS-543A (3/14-15)

Page 1 of 2

[FR Doc. 2015–13062 Filed 5–29–15; 8:45 am]
BILLING CODE 3410–30–C

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Rural Housing Service

Rural Utilities Service

Notice of Solicitation of Applications (NOSA) for the Strategic Economic and Community Development Programs for Fiscal Year (FY) 2015

AGENCY: Rural Business-Cooperative Service, Rural Housing Service, and Rural Utilities Service, USDA.

ACTION: Notice.

SUMMARY: Section 6025 of the Agricultural Act of 2014 (2014 Farm Bill) enables the Secretary of Agriculture to provide priority to projects that support Strategic Economic and Community Development plans. This Notice invites applicants who have submitted or will be submitting applications for the programs (referred to as ''underlying programs'') in Fiscal Year 2015.

For FY 2015, projects eligible for Section 6025 priority points will compete one time with all other projects eligible for the applicable underlying program's year-end pool of funds. These priority points are not eligible to projects competing for FY 2015 funding prior to the program's year-end pool of funds competition.

All applicants are responsible for any additional expenses incurred in preparing and submitting Form RD 1980–88.

DATES: To apply for Section 6025 priority points, applicants must submit Form RD 1980–88, ''Strategic Economic and Community Development (section 6025) Priority,'' by 5:00 p.m. Eastern Time on July 31, 2015.

ADDRESSES: Submit Form RD 1980–88 to the USDA Rural Development Area Office servicing the area where the project is located. A list of the USDA Rural Development Area Offices can be found listed by state at: *http://www.rd.usda.gov/contact-us/state-offices*.

FOR FURTHER INFORMATION CONTACT: Please contact the USDA Rural Development Area Office servicing the area where the project will be located.

SUPPLEMENTARY INFORMATION:

Overview

Solicitation Title: Strategic Economic and Community Development.

Announcement Type: Notice.

Catalog of Federal Domestic Assistance Number: 10.351, 10.760, 10.766 and 10.768.

All active CFDA programs can be found at *www.cfda.gov*.

Dates: For the list of dates please refer back to the summary section above.

Availability of Notice: This Notice is available through the USDA Rural Development Web site at *http://www.rd.usda.gov/about-rd/offices/community-economic-development*.

I. Funding Opportunity Description

A. Purpose

The purpose of Section 6025 of the 2014 Farm Bill is to give priority to projects that support strategic economic development or community development plans when applying for funds through the underlying programs. This Notice provides applicants with eligible projects the opportunity to receive additional priority when competing for one of the underlying program's year-end pool of funds for Fiscal Year 2015.

B. Statutory Authority

This priority is authorized under Section 6025 of the 2014 Farm Bill.

C. Programs

Based on Section 6025 of the 2014 Farm Bill, the Agency is making available additional priority points for projects that support strategic economic or community development plans to the following Rural Development programs:

- Community Facility Loans
- Fire and Rescue and Other Small Community Facilities Projects
- Community Facilities Grants
- Community Programs Guaranteed Loans
- Water and Waste Disposal Programs Guaranteed Loans
- Water and Waste Loans and Grants
- Business and Industry Guaranteed Loans
- Rural Business Development Grants

II. Award Information

Type of Awards: Guaranteed loans, direct loans and Grants.

Fiscal Year Funds: FY 2015; year-end pools of funds only.

Available Funds: The amount of funds available will depend on the amount of funds available at the time of year-end pooling and will vary among the underlying programs.

Award Amounts: Guaranteed loans, direct loans and grants will be awarded in amounts consistent with each applicable underlying program.

Award Dates: Awards will be made on or before September 30, 2015.

III. Eligibility Information

A. Eligible Requirements

In order to be considered for Section 6025 priority points, both the applicant and project must meet the eligibility requirements of the underlying program. These requirements vary among the underlying programs and the applicant is referred to the regulations for those programs.

The regulation implementing the Section 6025 priority does not make any changes to any of the applicant eligibility requirements of the underlying programs. However, the Section 6025 regulation does include three criteria that a project must meet in order to be considered for Section 6025 priority points (see 7 CFR 1980.1010).

The first criterion, as noted above, is that the project meets the applicable eligibility requirements of the underlying program for which the applicant is applying.

The second criterion is that the project is ''carried out solely in a rural area'' as defined in 7 CFR 1980.1005. As defined, this means either the entire project is physically located in a rural area or all of the beneficiaries of the service(s) provided through the project must either reside in or be located in a rural area. Note that the definition of ''rural'' varies among the underlying programs and the Section 6025 regulation does not change those definitions.

The third criterion is that the project support the implementation of a strategic economic development or community development plan on a multi-jurisdictional basis as defined in 7 CFR 1980.1005.

B. Cost Sharing or Matching

Any and all cost sharing, matching, and cost participation requirements of the applicable underlying program apply to projects seeking Section 6025 priority points. The Section 6025 regulation does not change such requirements.

C. Other Eligibility Requirements

Any and all other eligibility requirements (beyond those identified in III.A of this Notice) found in the underlying programs apply to applicants, their projects, and the beneficiaries of those projects are unchanged by either this Notice or the Section 6025 regulation.

IV. Form RD 1980–88

A. Address To Request Form RD 1980–88

Applicants responding to this Notice should contact the Rural Development

Area Office identified in the **ADDRESSES** portion of this Notice to obtain copies of Form RD 1980–88 and any supplemental information.

B. Content

To be considered for Section 6025 priority points, applicants must submit a complete Form RD 1980–88. This form requests such information as (see 7 CFR 1980.1015):

- Identification of whether the applicant includes a State, county, municipal, or tribal government;
- Identification by name of the plan being supported by the project, the date the plan became effective and is to remain in effect, and a detailed description of how the project directly supports one or more of the plan's objectives;
- Sufficient information to show that the project will be carried out solely in a rural area; and
- Identification of any current or previous applications the applicant has submitted for funds from the underlying programs.

C. Submission of Form RD 1980–88

If an applicant has already submitted an application for one of the underlying programs and the applicant wishes to be considered for Section 6025 priority points, that applicant must submit Form RD 1980–88 by close of business on the date listed in the **DATES** section of this Notice for that program.

If an applicant has not submitted an application for one of the underlying programs and that program is still accepting applications for FY 2015 funding, the applicant must submit Form RD 1980–88 at the same time the applicant submits the application material for the underlying program. However, in no case will Section 6025 priority points be considered for projects whose applications are received after close of business on the date listed in the **DATES** section of this Notice for the applicable program.

D. Completeness Eligibility

Failure to submit a complete Form RD 1980–88 may result in not receiving Section 6025 priority points.

V. Application Evaluation and Selection for Year-End Pool of Funds

All FY 2015 applications for underlying programs will be reviewed, evaluated, and scored based on the underlying program's scoring criteria. This Notice does not affect that process. This Notice only affects the scoring of applications being competed for an underlying program's year-end pool of funds.

A. Scoring of Applications

All eligible and complete applications competing for an underlying program's year-end pool of funds will be evaluated and scored based on the criteria of the applicable underlying program, whether or not the applicant seeks Section 6025 priority points by submitting Form RD 1980–88 in accordance with this Notice.

For applicants wishing to be considered for Section 6025 priority points as described in this Notice, the Agency will review, evaluate, and score each Form RD 1980–88 based on the criteria specified in 7 CFR 1980.1020. These criteria address:

- The proposed project's direct support of the objectives found in the strategic economic development or community development plan that it supports (7 CFR 1980.1020(b)(1)) and
- Certain characteristics (as specified in the authorizing statute) of strategic economic development or community plan that the proposed project support (7 CFR 1980.1020(b)(2)).

The scores from these two areas will be summed with the score derived from the underlying programs' criteria. Applications for the underlying programs that do not submit Form 1980–88 for Section 6025 priority will be scored based only on the applicable underlying program's scoring criteria. Thus, applications supplemented with Form RD 1980–88 will be eligible for a higher total score than applications without Form RD 1980–88 and will, in general, receive higher priority for funding.

B. Selection Process

The Agency will select the highest scoring applications competing for an underlying program's year-end pool of funds based on the award process for the underlying program to determine which projects receive funds except that:

- An application's total score will be determined in accordance with section V.A. of this Notice and
- To the extent provided by the underlying programs in this Notice, the Agency will encourage awarding ''Section 6025 priority'' applications in as many States and for as many of the underlying programs as possible by awarding discretionary points provided for diversification or other permissible purposes.

VI. Award Administration Information

A. Award Notices

The Agency will notify applicants who receive funding from the year-end pool of funds in a manner consistent with award notifications for the underlying program.

B. Administrative and National Policy Requirements

Any and all additional requirements of the applicable underlying programs apply to projects receiving funding in response to this Notice. Please see the regulations for the applicable underlying program.

C. Reporting Requirements

Any and all post-award reporting requirements contained in the underlying program apply to all projects receiving funding in response to this Notice.

Applicants who are selected for funding in response to this Notice (*i.e.,* those applicants who submit Form RD 1980–88 and receive funding from the underlying program's year-end pool of funds) are required to submit information in accordance with 7 CFR 1980.1026. This information is on the project's measures, metrics, and outcomes that the awardee would already be submitting to the appropriate entity(ies) monitoring the implementation of the plan.

VII. Agency Contacts

For general questions about this announcement, please contact your USDA Rural Development Area Office provided in the **ADDRESSES** section of this Notice.

VIII. Additional Information

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, the information collection requirements contained in 7 CFR part 1980, subpart K, have been approved by OMB under OMB Control Number 0570–0068 via emergency approval.

National Environmental Policy Act

This Notice of Solicitation of Applications has been reviewed in accordance with 7 CFR part 1940, subpart G, ''Environmental Program.'' The issuance of regulations and instructions, as well as amendments to them, describing administrative and financial procedures for the Agency's financial programs is categorically excluded in the Agency's NEPA regulation. Thus, in accordance with the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321–4347), the Agency has determined that this notice does not constitute a major Federal action significantly affecting the quality of the human environment.

Federal Funding Accountability and Transparency Act

All applicants, in accordance with 2 CFR part 25, must have a DUNS number, which can be obtained at no cost via a toll-free request line at 1–866–705–5711 or online at *http://fedgov.dnb.com/webor.* Similarly, all grant applicants must be registered in the System for Award Management (SAM) prior to submitting an application. Applicants may register for the SAM at *http://www.sam.gov.* All recipients of Federal financial grant assistance are required to report information about first-tier sub-awards and executive total compensation in accordance with 2 CFR part 170.

Nondiscrimination Statement

The U.S. Department of Agriculture (USDA) prohibits discrimination against its customers, employees, and applicants for employment on the bases of race, color, national origin, age, disability, sex, gender identity, religion, reprisal, and where applicable, political beliefs, marital status, familial or parental status, sexual orientation, or all or part of an individual's income is derived from any public assistance program, or protected genetic information in employment or in any program or activity conducted or funded by the Department. (Not all prohibited bases will apply to all programs and/or employment activities.)

If you wish to file a Civil Rights program complaint of discrimination, complete the USDA Program Discrimination Complaint Form (PDF), found online at *http://www.ascr.usda.gov/complaint_filing_cust.html,* or at any USDA office, or call (866) 632–9992 to request the form. You may also write a letter containing all of the information requested in the form. Send your completed complaint form or letter to us by mail at U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250–9410, by fax (202) 690–7442 or email at *program.intake@usda.gov.*

Individuals who are deaf, hard of hearing, or have speech disabilities and wish to file either an EEO or program complaint may contact USDA through the Federal Relay Service at (800) 877–8339 or (800) 845–6136 (in Spanish).

Persons with disabilities, who wish to file a program complaint, please see information above on how to contact us by mail directly or by email. If you require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, etc.) please contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Dated: May 22, 2015.

Lisa Mensah,

Under Secretary, Rural Development.

[FR Doc. 2015–13100 Filed 5–29–15; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, Department of Commerce.

ACTION: Notice and opportunity for public comment.

Pursuant to Section 251 of the Trade Act 1974, as amended (19 U.S.C. 2341 *et seq.*), the Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of these firms contributed importantly to the total or partial separation of the firm's workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE

[5/21/2015 through 5/26/2015]

Firm name	Firm address	Date accepted for investigation	Product(s)
Watch Enterprises, LLC dba Watch Technologies, LLC.	2185 Northeast Spalding #10, Grants Pass, OR 97526.	5/26/2015	The firm manufactures water/irrigation door/sluice gates and control actuators.
A Packaging Systems, LLC ...	1500 Lake Street, La Porte, IN 46350.	5/26/2015	The firm manufactures liquid filling, capping and labeling machinery.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance for Firms Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Dated: May 26, 2015.

Michael S. DeVillo,

Eligibility Examiner.

[FR Doc. 2015–13093 Filed 5–29–15; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Emerging Technology and Research Advisory Committee: Notice of Partially Closed Meeting

The Emerging Technology and Research Advisory Committee (ETRAC) will meet on June 18–19, 2015, 8:30 a.m., Room 3884, at the Herbert C. Hoover Building, 14th Street between Pennsylvania and Constitution Avenues NW., Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration on emerging technology and research activities, including those related to deemed exports.

Agenda

Thursday, June 18

Open Session

1. Welcome and Introductions.

2. Opening Remarks by the Assistant Secretary for Export Administration.

3. New Deemed Exports report.

4. Report on the June Conference by the Association of University Export Control Officials Review and discussion of new Export Control Reform Initiative Activities.

5. Comments from the Public.

6. Reports from ETRAC Committee members of their assigned Categories in reviewing the Export Administration Regulations.

7. Report on Air Force Office of Scientific Research-recent international technologies exchange meeting & Emerging Technologies under consideration.

Friday, June 19

Closed Session

8. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3).

The open sessions will be accessible via teleconference to 25 participants on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at *Yvette.Springer@bis.doc.gov* no later than, June 11, 2015.

A limited number of seats will be available for the public session. Reservations are not accepted. To the extent that time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate the distribution of public presentation materials to the Committee members, the Committee suggests that presenters forward the public presentation materials prior to the meeting to Ms. Springer via email.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on February 25, 2015, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended, that the portion of the meeting dealing with matters the of which would be likely to frustrate significantly implementation of a proposed agency action as described in 5 U.S.C. 552b(c)(9)(B) shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)1 and 10(a)(3). The remaining portions of the meeting will be open to the public.

For more information, call Yvette Springer at (202) 482–2813.

Dated: May 26, 2015.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2015–13130 Filed 5–29–15; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Five-Year (''Sunset'') Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: In accordance with section 751(c) of the Tariff Act of 1930, as amended (''the Act''), the Department of Commerce (''the Department'') is automatically initiating the five-year review (''Sunset Review'') of the antidumping and countervailing duty (''AD/CVD'') orders listed below. The International Trade Commission (''the Commission'') is publishing concurrently with this notice its notice of *Institution of Five-Year Review* which covers the same orders.

DATES: *Effective Date:* (June 1, 2015).

FOR FURTHER INFORMATION CONTACT: The Department official identified in the *Initiation of Review* section below at AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230. For information from the Commission contact Mary Messer, Office of Investigations, U.S. International Trade Commission at (202) 205–3193.

SUPPLEMENTARY INFORMATION:

Background

The Department's procedures for the conduct of Sunset Reviews are set forth in its *Procedures for Conducting Five-Year (''Sunset'') Reviews of Antidumping and Countervailing Duty Orders,* 63 FR 13516 (March 20, 1998) and 70 FR 62061 (October 28, 2005). Guidance on methodological or analytical issues relevant to the Department's conduct of Sunset Reviews is set forth in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101 (February 14, 2012).

Initiation of Review

In accordance with 19 CFR 351.218(c), we are initiating Sunset Reviews of the following antidumping and countervailing duty orders:

DOC case No.	ITC case No.	Country	Product	Department contact
A–570–962	731–TA–1173	PRC	Potassium Phosphate Salts (1st Review)	Matthew Renkey (202) 482–2312.
C–570–963	701–TA–473	PRC	Potassium Phosphate Salts (1st Review)	Jacqueline Arrowsmith (202) 482–5255.
A–570–947	731–TA–1161	PRC	Steel Grating (1st Review)	Matthew Renkey (202) 482–2312.
C–570–948	701–TA–465	PRC	Steel Grating (1st Review)	Jacqueline Arrowsmith (202) 482–5255.
A–570–894	731–TA–1070B	PRC	Tissue Paper Products (2nd Review)	David Goldberger (202) 482–4136.

Filing Information

As a courtesy, we are making information related to sunset proceedings, including copies of the pertinent statute and Department's regulations, the Department's schedule for Sunset Reviews, a listing of past revocations and continuations, and current service lists, available to the public on the Department's Web site at the following address: ''*http://enforcement.trade.gov/sunset/.*'' All submissions in these Sunset Reviews must be filed in accordance with the Department's regulations regarding format, translation, and service of documents. These rules, including electronic filing requirements via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''ACCESS''), can be found at 19 CFR 351.303.[1]

Revised Factual Information Requirements

This notice serves as a reminder that any party submitting factual information in an AD/CVD proceeding must certify to the accuracy and completeness of that information.[2] Parties are hereby reminded that revised certification requirements are in effect for company/

[1] *See also Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

[2] *See* section 782(b) of the Act.

government officials as well as their representatives in all AD/CVD investigations or proceedings initiated on or after August 16, 2013.[3] The formats for the revised certifications are provided at the end of the *Final Rule.* The Department intends to reject factual submissions if the submitting party does not comply with the revised certification requirements.

On April 10, 2013, the Department published *Definition of Factual Information and Time Limits for Submission of Factual Information: Final Rule,* 78 FR 21246 (April 10, 2013), which modified two regulations related to antidumping and countervailing duty proceedings: the definition of factual information (19 CFR 351.102(b)(21), and the time limits for the submission of factual information (19 CFR 351.301). The final rule identifies five categories of factual information in 19 CFR 351.102(b)(21), which are summarized as follows: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by the Department; and (v) evidence other than factual information described in (i)–(iv). The final rule requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. The final rule also modified 19 CFR 351.301 so that, rather than providing general time limits, there are specific time limits based on the type of factual information being submitted. These modifications are effective for all segments initiated on or after May 10, 2013. Review the final rule, available at *http://enforcement.trade.gov/frn/2013/1304frn/2013-08227.txt,* prior to submitting factual information in this segment. To the extent that other regulations govern the submission of factual information in a segment (such as 19 CFR 351.218), these time limits will continue to be applied.

[3] *See Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (''*Final Rule*'') (amending 19 CFR 351.303(g)).

Revised Extension of Time Limits Regulation

On September 20, 2013, the Department modified its regulation at 19 CFR 351.302(c) concerning the extension of time limits for submissions in antidumping and countervailing duty proceedings: *Extension of Time Limits,* 78 FR 57790 (September 20, 2013). The modification clarifies that parties may request an extension of time limits before a time limit established under part 351 of the Department's regulations expires, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the time limit established under part 351 expires. For submissions which are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Under certain circumstances, the Department may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, the Department will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. This modification also requires that an extension request must be made in a separate, stand-alone submission, and clarifies the circumstances under which the Department will grant untimely-filed requests for the extension of time limits. These modifications are effective for all segments initiated on or after October 21, 2013. Review the final rule, available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in these segments.

Letters of Appearance and Administrative Protective Orders

Pursuant to 19 CFR 351.103(d), the Department will maintain and make available a public service list for these proceedings. Parties wishing to participate in any of these five-year reviews must file letters of appearance as discussed at 19 CFR 351.103(d)). To facilitate the timely preparation of the public service list, it is requested that those seeking recognition as interested parties to a proceeding submit an entry of appearance within 10 days of the publication of the Notice of Initiation.

Because deadlines in Sunset Reviews can be very short, we urge interested parties who want access to proprietary information under administrative protective order (''APO'') to file an APO application immediately following publication in the **Federal Register** of this notice of initiation. The Department's regulations on submission of proprietary information and eligibility to receive access to business proprietary information under APO can be found at 19 CFR 351.304–306.

Information Required From Interested Parties

Domestic interested parties, as defined in section 771(9)(C), (D), (E), (F), and (G) of the Act and 19 CFR 351.102(b), wishing to participate in a Sunset Review must respond not later than 15 days after the date of publication in the **Federal Register** of this notice of initiation by filing a notice of intent to participate. The required contents of the notice of intent to participate are set forth at 19 CFR 351.218(d)(1)(ii). In accordance with the Department's regulations, if we do not receive a notice of intent to participate from at least one domestic interested party by the 15-day deadline, the Department will automatically revoke the order without further review.[4]

If we receive an order-specific notice of intent to participate from a domestic interested party, the Department's regulations provide that *all parties* wishing to participate in a Sunset Review must file complete substantive responses not later than 30 days after the date of publication in the **Federal Register** of this notice of initiation. The required contents of a substantive response, on an order-specific basis, are set forth at 19 CFR 351.218(d)(3). Note that certain information requirements differ for respondent and domestic parties. Also, note that the Department's information requirements are distinct from the Commission's information requirements. Consult the Department's regulations for information regarding the Department's conduct of Sunset Reviews. Consult the Department's regulations at 19 CFR part 351 for definitions of terms and for other general information concerning antidumping and countervailing duty proceedings at the Department.

This notice of initiation is being published in accordance with section 751(c) of the Act and 19 CFR 351.218(c).

Dated: May 18, 2015.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2015–13111 Filed 5–29–15; 8:45 am]

BILLING CODE 3510–DS–P

[4] *See* 19 CFR 351.218(d)(1)(iii).

DEPARTMENT OF COMMERCE

International Trade Administration

Environmental Technologies Trade Advisory Committee Public Meeting

AGENCY: International Trade Administration, DOC.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a meeting of the Environmental Technologies Trade Advisory Committee (ETTAC).

DATES: The meeting is scheduled for Tuesday, June 30, 2015, at 8:30 a.m. Eastern Daylight Time (EDT).

ADDRESSES: The meeting will be held in Room 4830 at the U.S. Department of Commerce, Herbert Clark Hoover Building, 1401 Constitution Avenue NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Ms. Maureen Hinman, Office of Energy & Environmental Industries (OEEI), International Trade Administration, Room 4053, 1401 Constitution Avenue NW., Washington, DC 20230 (Phone: 202–482–0627; Fax: 202–482–5665; email: *maureen.hinman@trade.gov*.) This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to OEEI at (202) 482–5225 no less than one week prior to the meeting.

SUPPLEMENTARY INFORMATION: The meeting will take place from 8:30 a.m. to 3:30 p.m. EDT. The general meeting is open to the public and time will be permitted for public comment from 3:00–3:30 p.m. EDT. Those interested in attending must provide notification by Friday, June 12, 2015 at 5:00 p.m. EDT, via the contact information provided above. Written comments concerning ETTAC affairs are welcome any time before or after the meeting. Minutes will be available within 30 days of this meeting.

Topics to be considered: The agenda for the Tuesday, June 30, 2015 ETTAC meeting is as follows:

8:30 a.m.–3:30 p.m.

1. Discussion of priorities and objectives for the committee
2. Status updates on ongoing trade negotiations related to environmental technologies
3. Subcommittee working meetings

Background: The ETTAC is mandated by Public Law 103–392. It was created to advise the U.S. government on environmental trade policies and programs, and to help it to focus its resources on increasing the exports of the U.S. environmental industry. ETTAC operates as an advisory committee to the Secretary of Commerce and the Trade Promotion Coordinating Committee (TPCC). ETTAC was originally chartered in May of 1994. It was most recently re-chartered until August 2016.

Edward A. O'Malley,

Office Director, Office of Energy and Environmental Industries.

[FR Doc. 2015–13158 Filed 5–29–15; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–890]

Wooden Bedroom Furniture From the People's Republic of China: Notice of Initiation of Changed Circumstances Review, and Consideration of Revocation of the Antidumping Duty Order in Part

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Based on a request from Ololo, Inc., (''Ololo'') the Department of Commerce (the ''Department'') is initiating a changed circumstances review to consider the possible revocation, in part, of the antidumping duty (''AD'') order on wooden bedroom furniture from the People's Republic of China (''PRC'') with respect to certain bed bases.

DATES: *Effective Date:* June 1, 2015.

FOR FURTHER INFORMATION CONTACT: Howard Smith or Valerie Ellis, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–5193 or (202) 482–4551, respectively.

SUPPLEMENTARY INFORMATION:

Background

On January 4, 2005, the Department published the *Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Wooden Bedroom Furniture From the People's Republic of China,* 70 FR 329 (January 4, 2005). On April 10, 2015, Ololo, an importer of the subject merchandise, requested revocation, in part, of the AD order pursuant to section 751(b)(1) of the Tariff Act of 1930, as amended (''the Act'') and 19 CFR 351.216(b), with respect to bed bases consisting of: (1) A wooden box frame, (2) three wooden cross beams and one perpendicular center wooden support beam, and (3) wooden slats over the beams. These bed bases are constructed without inner springs and/or coils and do not include a headboard, footboard, side rails, or mattress. The bed bases are imported unassembled. On April 27, 2015, the American Furniture Manufacturers Committee for Legal Trade and Vaughan-Bassett Furniture Company, Inc. (collectively, ''Petitioners'') stated that they agree with the scope exclusion language proposed by Ololo for certain bed bases.[1]

Scope of the Order

The product covered by the order is wooden bedroom furniture. Wooden bedroom furniture is generally, but not exclusively, designed, manufactured, and offered for sale in coordinated groups, or bedrooms, in which all of the individual pieces are of approximately the same style and approximately the same material and/or finish. The subject merchandise is made substantially of wood products, including both solid wood and also engineered wood products made from wood particles, fibers, or other wooden materials such as plywood, strand board, particle board, and fiberboard, with or without wood veneers, wood overlays, or laminates, with or without non-wood components or trim such as metal, marble, leather, glass, plastic, or other resins, and whether or not assembled, completed, or finished.

The subject merchandise includes the following items: (1) Wooden beds such as loft beds, bunk beds, and other beds; (2) wooden headboards for beds (whether stand-alone or attached to side rails), wooden footboards for beds, wooden side rails for beds, and wooden canopies for beds; (3) night tables, night stands, dressers, commodes, bureaus, mule chests, gentlemen's chests, bachelor's chests, lingerie chests, wardrobes, vanities, chessers, chifforobes, and wardrobe-type cabinets; (4) dressers with framed glass mirrors that are attached to, incorporated in, sit on, or hang over the dresser; (5) chests-

[1] *See* April 27, 2015 letter from Petitioners Re: Wooden Bedroom Furniture From The People's Republic of China/Petitioners' Response to Ololo's Letter of April 10, 2015.

on-chests,[2] highboys,[3] lowboys,[4] chests of drawers,[5] chests,[6] door chests,[7] chiffoniers,[8] hutches,[9] and armoires; [10] (6) desks, computer stands, filing cabinets, book cases, or writing tables that are attached to or incorporated in the subject merchandise; and (7) other bedroom furniture consistent with the above list.

The scope of the order excludes the following items: (1) Seats, chairs, benches, couches, sofas, sofa beds, stools, and other seating furniture; (2) mattresses, mattress supports (including box springs), infant cribs, water beds, and futon frames; (3) office furniture, such as desks, stand-up desks, computer cabinets, filing cabinets, credenzas, and bookcases; (4) dining room or kitchen furniture such as dining tables, chairs, servers, sideboards, buffets, corner cabinets, china cabinets, and china hutches; (5) other non-bedroom furniture, such as television cabinets, cocktail tables, end tables, occasional tables, wall systems, book cases, and entertainment systems; (6) bedroom furniture made primarily of wicker, cane, osier, bamboo or rattan; (7) side rails for beds made of metal if sold separately from the headboard and footboard; (8) bedroom furniture in which bentwood parts predominate; [11] (9) jewelry armories; [12] (10) cheval mirrors; [13] (11) certain metal parts; [14] (12) mirrors that do not attach to, incorporate in, sit on, or hang over a dresser if they are not designed and marketed to be sold in conjunction with a dresser as part of a dresser-mirror set; (13) upholstered beds; [15] (14) toy boxes; [16] (15) enclosable wall bed units; [17] and (16) shoe cabinets.[18] Imports of subject merchandise are classified under subheadings 9403.50.9042 and 9403.50.9045 of the HTSUS as ''wooden . . . beds'' and under subheading 9403.50.9080 of the HTSUS as ''other . . . wooden furniture of a kind used in the bedroom.'' In addition, wooden headboards for beds, wooden footboards for beds, wooden side rails for beds, and wooden canopies for beds may also be entered under subheading 9403.50.9042 or 9403.50.9045 of the HTSUS as ''parts of wood.'' Subject merchandise may also be entered under subheadings 9403.50.9041, 9403.60.8081, or 9403.20.0018, or 9403.90.8041. Further, framed glass mirrors may be entered under subheading 7009.92.1000 or 7009.92.5000 of the HTSUS as ''glass mirrors . . . framed.'' The order covers all wooden bedroom furniture meeting

[2] A chest-on-chest is typically a tall chest-of-drawers in two or more sections (or appearing to be in two or more sections), with one or two sections mounted (or appearing to be mounted) on a slightly larger chest; also known as a tallboy.

[3] A highboy is typically a tall chest of drawers usually composed of a base and a top section with drawers, and supported on four legs or a small chest (often 15 inches or more in height).

[4] A lowboy is typically a short chest of drawers, not more than four feet high, normally set on short legs.

[5] A chest of drawers is typically a case containing drawers for storing clothing.

[6] A chest is typically a case piece taller than it is wide featuring a series of drawers and with or without one or more doors for storing clothing. The piece can either include drawers or be designed as a large box incorporating a lid.

[7] A door chest is typically a chest with hinged doors to store clothing, whether or not containing drawers. The piece may also include shelves for televisions and other entertainment electronics.

[8] A chiffonier is typically a tall and narrow chest of drawers normally used for storing undergarments and lingerie, often with mirror(s) attached.

[9] A hutch is typically an open case of furniture with shelves that typically sits on another piece of furniture and provides storage for clothes.

[10] An armoire is typically a tall cabinet or wardrobe (typically 50 inches or taller), with doors, and with one or more drawers (either exterior below or above the doors or interior behind the doors), shelves, and/or garment rods or other apparatus for storing clothes. Bedroom armoires may also be used to hold television receivers and/or other audio-visual entertainment systems.

[11] As used herein, bentwood means solid wood made pliable. Bentwood is wood that is brought to a curved shape by bending it while made pliable with moist heat or other agency and then set by cooling or drying. *See* CBP's Headquarters Ruling Letter 043859, dated May 17, 1976.

[12] Any armoire, cabinet or other accent item for the purpose of storing jewelry, not to exceed 24 inches in width, 18 inches in depth, and 49 inches in height, including a minimum of 5 lined drawers lined with felt or felt-like material, at least one side door (whether or not the door is lined with felt or felt-like material), with necklace hangers, and a flip-top lid with inset mirror. *See* Issues and Decision Memorandum from Laurel LaCivita to Laurie Parkhill, Office Director, concerning ''Jewelry Armoires and Cheval Mirrors in the Antidumping Duty Investigation of Wooden Bedroom Furniture from the People's Republic of China,'' dated August 31, 2004. *See also Wooden Bedroom Furniture From the People's Republic of China: Final Changed Circumstances Review, and Determination To Revoke Order in Part,* 71 FR 38621 (July 7, 2006).

[13] Cheval mirrors are any framed, tiltable mirror with a height in excess of 50 inches that is mounted on a floor-standing, hinged base. Additionally, the scope of the order excludes combination cheval mirror/jewelry cabinets. The excluded merchandise is an integrated piece consisting of a cheval mirror, *i.e.,* a framed tiltable mirror with a height in excess of 50 inches, mounted on a floor-standing, hinged base, the cheval mirror serving as a door to a cabinet back that is integral to the structure of the mirror and which constitutes a jewelry cabinet line with fabric, having necklace and bracelet hooks, mountings for rings and shelves, with or without a working lock and key to secure the contents of the jewelry cabinet back to the cheval mirror, and no drawers anywhere on the integrated piece. The fully assembled piece must be at least 50 inches in height, 14.5 inches in width, and 3 inches in depth. *See Wooden Bedroom Furniture From the People's Republic of China: Final Changed Circumstances Review and Determination To Revoke Order in Part,* 72 FR 948 (January 9, 2007).

[14] Metal furniture parts and unfinished furniture parts made of wood products (as defined above) that are not otherwise specifically named in this scope (*i.e.,* wooden headboards for beds, wooden footboards for beds, wooden side rails for beds, and wooden canopies for beds) and that do not possess the essential character of wooden bedroom furniture in an unassembled, incomplete, or unfinished form. Such parts are usually classified under HTSUS subheadings 9403.90.7005, 9403.90.7010, or 9403.90.7080.

[15] Upholstered beds that are completely upholstered, *i.e.,* containing filling material and completely covered in sewn genuine leather, synthetic leather, or natural or synthetic decorative fabric. To be excluded, the entire bed (headboards, footboards, and side rails) must be upholstered except for bed feet, which may be of wood, metal, or any other material and which are no more than nine inches in height from the floor. *See Wooden Bedroom Furniture from the People's Republic of China: Final Results of Changed Circumstances Review and Determination to Revoke Order in Part,* 72 FR 7013 (February 14, 2007).

[16] To be excluded the toy box must: (1) Be wider than it is tall; (2) have dimensions within 16 inches to 27 inches in height, 15 inches to 18 inches in depth, and 21 inches to 30 inches in width; (3) have a hinged lid that encompasses the entire top of the box; (4) not incorporate any doors or drawers; (5) have slow-closing safety hinges; (6) have air vents; (7) have no locking mechanism; and (8) comply with American Society for Testing and Materials (''ASTM'') standard F963–03. Toy boxes are boxes generally designed for the purpose of storing children's items such as toys, books, and playthings. *See Wooden Bedroom Furniture from the People's Republic of China: Final Results of Changed Circumstances Review and Determination to Revoke Order in Part,* 74 FR 8506 (February 25, 2009). Further, as determined in the scope ruling memorandum ''Wooden Bedroom Furniture from the People's Republic of China: Scope Ruling on a White Toy Box,'' dated July 6, 2009, the dimensional ranges used to identify the toy boxes that are excluded from the wooden bedroom furniture order apply to the box itself rather than the lid.

[17] Enclosable wall bed units, also referred to as murphy beds, are composed of the following three major sections: (1) A metal wall frame, which attaches to the wall and uses coils or pistons to support the metal mattress frame; (2) a metal frame, which has euro slats for supporting a mattress and two legs that pivot; and (3) wood panels, which attach to the metal wall frame and/or the metal mattress frame to form a cabinet to enclose the wall bed when not in use. Excluded enclosable wall bed units are imported in ready-to-assemble format with all parts necessary for assembly. Enclosable wall bed units do not include a mattress. Wood panels of enclosable wall bed units, when imported separately, remain subject to the order. *See Wooden Bedroom Furniture From the People's Republic of China: Final Results of Changed Circumstances Review, and Revocation of Antidumping Duty Order, in Part,* 79 FR 64569 (October 30, 2014).

[18] Excluded shoe cabinets are 31.5–33.5 inches wide by 15.5–17.5 inches deep by 34.5–36.5 inches high. They are designed strictly to store shoes, which are intended to be aligned in rows perpendicular to the wall along which the cabinet is positioned. Shoe cabinets do not have drawers, rods, or other indicia for the storage of clothing other than shoes. The cabinets are not designed, manufactured, or offered for sale in coordinated groups or sets and are made substantially of wood, have two to four shelves inside them, and are covered by doors. The doors often have blinds that are designed to allow air circulation and release of bad odors. The doors themselves may be made of wood or glass. The depth of the shelves does not exceed 14 inches. Each shoe cabinet has doors, adjustable shelving, and ventilation holes. *See Wooden Bedroom Furniture From the People's Republic of China: Final Results of Changed Circumstances Review, and Revocation of Antidumping Duty Order, in Part,* 80 FR 18383 (April 6, 2015).

the above description, regardless of tariff classification. Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Initiation of Changed Circumstances Review, and Consideration of Revocation of the Order in Part

Pursuant to section 751(b) of the Act, the Department will conduct a changed circumstances review upon receipt of a request from an interested party [19] which shows changed circumstances sufficient to warrant a review of an order.[20] Based on the information provided by Ololllo, the Department has determined that there exist changed circumstances sufficient to warrant a changed circumstances review of the AD order on wooden bedroom furniture from the PRC.[21]

Section 782(h)(2) of the Act and 19 CFR 351.222(g)(1)(i) provide that the Department may revoke an order (in whole or in part) if it determines that producers accounting for substantially all of the production of the domestic like product have expressed a lack of interest in the order, in whole or in part. In addition, in the event the Department determines that expedited action is warranted, 19 CFR 351.221(c)(3)(ii) permits the Department to combine the notices of initiation and preliminary results. In its administrative practice, the Department has interpreted ''substantially all'' to mean producers accounting for at least 85 percent of the total U.S. production of the domestic like product covered by the order.[22] Petitioners state that they agree with the exclusion request, however, because Petitioners did not indicate whether they account for substantially all of the domestic production of wooden bedroom furniture, we are providing interested parties with the opportunity to address the issue of domestic industry support with respect to this proposed partial revocation of the order, and we are not combining this notice of initiation with a preliminary determination pursuant to 19 CFR 351.221(c)(3)(ii). As explained below, this notice of initiation will afford all interested parties an opportunity to address the proposed partial revocation.

Public Comment

Interested parties are invited to provide comments and/or factual information regarding this changed circumstances review, including comments concerning industry support. Comments and factual information may be submitted to the Department no later than 14 days after the date of publication of this notice. Rebuttal comments and rebuttal factual information may be filed with the Department no later than 10 days after the comments and/or factual information are filed.[23] All submissions must be filed electronically using Enforcement and Compliance's AD and CVD Centralized Electronic Service System (ACCESS).[24] An electronically filed document must be received successfully in its entirety by ACCESS, by 5 p.m. Eastern Time on the due dates set forth in this notice.

The Department will issue the preliminary results of this changed circumstances review, in accordance with 19 CFR 351.221(c)(3), which will set forth the factual and legal conclusions upon which the preliminary results are based, and a description of any action proposed because of those results. Pursuant to 19 CFR 351.221(b)(4)(ii), interested parties will have an opportunity to comment on the preliminary results of the review. In accordance with 19 CFR 351.216(e), the Department will issue the final results of its AD changed circumstance review within 270 days after the date on which the review is initiated.

This initiation is published in accordance with section 751(b)(1) of the Act and 19 CFR 351.221(b)(1).

Dated: May 22, 2015.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2015–13107 Filed 5–29–15; 8:45 am]

BILLING CODE 3510–DS–P

[19] Ololllo stated in its April 29, 2015 entry of appearance that it is an importer of subject merchandise and as such is an interested party pursuant to 19 CFR 351.102(a)(29)(ii).

[20] *See* 19 CFR 351.216.

[21] *See* section 751(b) of the Act and 19 CFR 351.216(d).

[22] *See, e.g., Certain Cased Pencils From the People's Republic of China: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review, and Intent To Revoke Order in Part,* 77 FR 42276 (July 18, 2012) (*Pencils*), unchanged in *Certain Cased Pencils From the People's Republic of China: Final Results of Antidumping Duty Changed Circumstances Review, and Determination To Revoke Order, in Part,* 77 FR 53176 (August 31, 2012).

[23] *See* 19 CFR 351.301(b)(2)

[24] *See,* generally, 19 CFR 351.303.

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Advance Notification of Sunset Reviews

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

Background

Every five years, pursuant to section 751(c) of the Tariff Act of 1930, as amended (''the Act''), the Department of Commerce (''the Department'') and the International Trade Commission automatically initiate and conduct a review to determine whether revocation of a countervailing or antidumping duty order or termination of an investigation suspended under section 704 or 734 of the Act would be likely to lead to continuation or recurrence of dumping or a countervailable subsidy (as the case may be) and of material injury.

Upcoming Sunset Reviews for July 2015

The following Sunset Reviews are scheduled for initiation in July 2015 and will appear in that month's Notice of Initiation of Five-Year Sunset Review (''Sunset Review'').

Antidumping Duty Proceedings

Woven Electric Blankets from China (A–570–951) (1st Review)

Department Contact

Matthew Renkey, (202) 482–2312.

Countervailing Duty Proceedings

No Sunset Review of countervailing duty orders is scheduled for initiation in July 2015.

Suspended Investigations

No Sunset Review of suspended investigations is scheduled for initiation in July 2015.

The Department's procedures for the conduct of Sunset Reviews are set forth in 19 CFR 351.218. The Notice of Initiation of Five-Year (''Sunset'') Reviews provides further information regarding what is required of all parties to participate in Sunset Reviews.

Pursuant to 19 CFR 351.103(c), the Department will maintain and make available a service list for these proceedings. To facilitate the timely preparation of the service list(s), it is requested that those seeking recognition as interested parties to a proceeding contact the Department in writing within 10 days of the publication of the Notice of Initiation.

Please note that if the Department receives a Notice of Intent to Participate from a member of the domestic industry within 15 days of the date of initiation, the review will continue. Thereafter, any interested party wishing to participate in the Sunset Review must provide substantive comments in response to the notice of initiation no later than 30 days after the date of initiation.

This notice is not required by statute but is published as a service to the international trading community.

Dated: May 18, 2015.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2015–13122 Filed 5–29–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–602–807, A–351–842, A–570–022, A–560–828, A–471–807]

Certain Uncoated Paper From Australia, Brazil, the People's Republic of China, Indonesia, and Portugal: Postponement of Preliminary Determinations of Antidumping Duty Investigations

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* June 1, 2015.

FOR FURTHER INFORMATION CONTACT: Eve Wang at (202) 482–6231 (Australia); Julia Hancock at (202) 482–1394 (Brazil); Stephanie Moore at (202) 482–3692 (the People's Republic of China (PRC)); Blaine Wiltse at (202) 482–6345 (Indonesia); and Kabir Archuletta at (202) 482–2593 (Portugal), AD/CVD Operations, Enforcement and Compliance, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On February 10, 2015, the Department of Commerce (the Department) initiated antidumping duty (AD) investigations of imports of certain uncoated paper (uncoated paper) from Australia, Brazil, the PRC, Indonesia, and Portugal.[1] The notice of initiation stated that, in accordance with section 733(b)(1)(A) of the Act and 19 CFR 351.205(b)(1), we would issue our preliminary determinations no later than 140 days after the date of initiation, unless postponed. Currently, the preliminary determinations in these investigations are due no later than June 30, 2015.

Postponement of Preliminary Determinations

Section 733(b)(1)(A) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.205(b)(1), require the Department to issue the preliminary determination in an AD investigation within 140 days after the date on which the Department initiated the investigation. However, if the petitioner makes a timely request for an extension in accordance with 19 CFR 351.205(e), section 733(c)(1)(A) of the Act allows the Department to postpone the preliminary determination until no later than 190 days after the date on which the Department initiated the investigation.

On May 15, 2015 and May 18, 2015, United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union (USW); Domtar Corporation; Finch Paper LLC; P.H. Glatfelter Company; and Packaging Corporation of America (collectively, the ''petitioners'') made timely requests, pursuant to section 733(c)(1)(A) of the Act and 19 CFR 351.205(e), for a 50-day postponement of the preliminary determinations in the investigations.[2] The petitioners stated that a postponement of the preliminary determinations in all five of the uncoated paper AD investigations is necessary because it may not be feasible for the Department to analyze questionnaire responses, identify issues, and develop the respective case records of the aforementioned investigations as necessary within the current schedule.[3] With respect to the AD investigation of uncoated paper from the PRC, the petitioners indicated that a postponement is warranted because it is not feasible to resolve the necessary surrogate country selection and valuation issues within the current schedule.[4]

Under section 733(c)(1)(A) of the Act, if a petitioner makes a timely request for an extension of the period within which the preliminary determination must be made under subsection (b)(1), then the Department may postpone making the preliminary determination under subsection (b)(1) until not later than the 190th day after the date on which the administering authority initiated the investigation. Therefore, for the reasons stated above, and because we find there are no compelling reasons to deny the petitioners' requests, the Department is postponing the preliminary determinations in these investigations until August 19, 2015, which is 190 days from the date on which the Department initiated these investigations.

Pursuant to section 735(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determinations will continue to be 75 days after the date of the preliminary determinations, unless this deadline is extended.

This notice is issued and published pursuant to section 733(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: May 21, 2015.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2015–13044 Filed 5–29–15; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Certain Uncoated Paper from Australia, Brazil, the People's Republic of China, Indonesia, and Portugal: Initiation of Less-Than-Fair-Value Investigations,* 80 FR 8608 (February 18, 2015).

[2] *See* petitioners' letters to the Department dated May 15, 2015 and May 18, 2015.

[3] *Id.*

[4] *See* petitioners' letter to the Department dated May 18, 2015 at 1.

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

FOR FURTHER INFORMATION CONTACT: Brenda E. Waters, Office of AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, telephone: (202) 482–4735.

Background

Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspended investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended (''the Act''), may request, in accordance with 19 CFR 351.213, that the Department of Commerce (''the Department'') conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

All deadlines for the submission of comments or actions by the Department discussed below refer to the number of

calendar days from the applicable starting date.

Respondent Selection

In the event the Department limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, the Department intends to select respondents based on U.S. Customs and Border Protection (''CBP'') data for U.S. imports during the period of review. We intend to release the CBP data under Administrative Protective Order (''APO'') to all parties having an APO within five days of publication of the initiation notice and to make our decision regarding respondent selection within 21 days of publication of the initiation **Federal Register** notice. Therefore, we encourage all parties interested in commenting on respondent selection to submit their APO applications on the date of publication of the initiation notice, or as soon thereafter as possible. The Department invites comments regarding the CBP data and respondent selection within five days of placement of the CBP data on the record of the review.

In the event the Department decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

In general, the Department finds that determinations concerning whether particular companies should be ''collapsed'' (*i.e.,* treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, the Department will not conduct collapsing analyses at the respondent selection phase of this review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (*i.e.,* investigation, administrative review, new shipper review or changed circumstances review). For any company subject to this review, if the Department determined, or continued to treat, that company as collapsed with others, the Department will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, the Department will not collapse companies for purposes of respondent selection. Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete the Quantity and Value Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of this proceeding where the Department considered collapsing that entity, complete quantity and value data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that requests a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that the Department may extend this time if it is reasonable to do so. In order to provide parties additional certainty with respect to when the Department will exercise its discretion to extend this 90-day deadline, interested parties are advised that, with regard to reviews requested on the basis of anniversary months on or after June 2015, the Department does not intend to extend the 90-day deadline unless the requestor demonstrates that an extraordinary circumstance prevented it from submitting a timely withdrawal request. Determinations by the Department to extend the 90-day deadline will be made on a case-by-case basis.

The Department is providing this notice on its Web site, as well as in its ''Opportunity to Request Administrative Review'' notices, so that interested parties will be aware of the manner in which the Department intends to exercise its discretion in the future.

Opportunity To Request a Review: Not later than the last day of June 2015,[1] interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in June for the following periods:

	Period of review
Antidumping Duty Proceedings	
JAPAN:	
Carbon and Alloy Seamless Standard, Line, and Pressure Pipe, A–588–850 (Over 4½ Inches)	6/1/14–5/31/15
Carbon and Alloy Seamless Standard, Line and Pressure Pipe, A–588–851 (Under 4½ Inches)	6/1/14–5/31/15
MEXICO: Prestressed Concrete Steel Rail Tie Wire, A–201–843	12/12/13–5/31/15
SPAIN: Chlorinated Isocyanurates, A–469–814	6/1/14–5/31/15
TAIWAN: Helical Spring Lock Washers, A–583–820	6/1/14–5/31/15
THE PEOPLE'S REPUBLIC OF CHINA:	
Artist Canvas, A–570–899	6/1/14–5/31/15
Chlorinated Isocyanurates, A–570–898	6/1/14–5/31/15
Furfuryl Alcohol, A–570–835	6/1/14–5/31/15
High Pressure Steel Cylinders, A–570–977	6/1/14–5/31/15
Polyester Staple Fiber, A–570–905	6/1/14–5/31/15
Prestressed Concrete Steel Rail Tie Wire, A–570–990	12/12/13–5/31/15
Prestressed Concrete Steel Wire Strand, A–570–945	6/1/14–5/31/15
Silicon Metal, A–570–806	6/1/14–5/31/15
Tapered Roller Bearings, A–570–601	6/1/14–5/31/15
Countervailing Duty Proceedings	
THE PEOPLE'S REPUBLIC OF CHINA: High Pressure Steel Cylinders, C–570–978	1/1/14–12/31/14

[1] Or the next business day, if the deadline falls on a weekend, federal holiday or any other day when the Department is closed.

	Period of review
Suspension Agreements	
None.	

In accordance with 19 CFR 351.213(b), an interested party as defined by section 771(9) of the Act may request in writing that the Secretary conduct an administrative review. For both antidumping and countervailing duty reviews, the interested party must specify the individual producers or exporters covered by an antidumping finding or an antidumping or countervailing duty order or suspension agreement for which it is requesting a review. In addition, a domestic interested party or an interested party described in section 771(9)(B) of the Act must state why it desires the Secretary to review those particular producers or exporters. If the interested party intends for the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which was produced in more than one country of origin and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Note that, for any party the Department was unable to locate in prior segments, the Department will not accept a request for an administrative review of that party absent new information as to the party's location. Moreover, if the interested party who files a request for review is unable to locate the producer or exporter for which it requested the review, the interested party must provide an explanation of the attempts it made to locate the producer or exporter at the same time it files its request for review, in order for the Secretary to determine if the interested party's attempts were reasonable, pursuant to 19 CFR 351.303(f)(3)(ii).

As explained in *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003), and *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011) the Department clarified its practice with respect to the collection of final antidumping duties on imports of merchandise where intermediate firms are involved. The public should be aware of this clarification in determining whether to request an administrative review of merchandise subject to antidumping findings and orders.[2]

Further, as explained in *Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013), the Department clarified its practice with regard to the conditional review of the non-market economy (NME) entity in administrative reviews of antidumping duty orders. The Department will no longer consider the NME entity as an exporter conditionally subject to administrative reviews. Accordingly, the NME entity will not be under review unless the Department specifically receives a request for, or self-initiates, a review of the NME entity.[3] In administrative reviews of antidumping duty orders on merchandise from NME countries where a review of the NME entity has not been initiated, but where an individual exporter for which a review was initiated does not qualify for a separate rate, the Department will issue a final decision indicating that the company in question is part of the NME entity. However, in that situation, because no review of the NME entity was conducted, the NME entity's entries were not subject to the review and the rate for the NME entity is not subject to change as a result of that review (although the rate for the individual exporter may change as a function of the finding that the exporter is part of the NME entity).

Following initiation of an antidumping administrative review when there is no review requested of the NME entity, the Department will instruct CBP to liquidate entries for all exporters not named in the initiation notice, including those that were suspended at the NME entity rate.

All requests must be filed electronically in Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''ACCESS'') on Enforcement and Compliance's ACCESS Web site at *http://access.trade.gov.*[4] Further, in accordance with 19 CFR 351.303(f)(l)(i), a copy of each request must be served on the petitioner and each exporter or producer specified in the request.

The Department will publish in the **Federal Register** a notice of ''Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation'' for requests received by the last day of June 2015. If the Department does not receive, by the last day of June 2015, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, the Department will instruct CBP to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of (or bond for) estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures ''gap'' period of the order, if such a gap period is applicable to the period of review.

This notice is not required by statute but is published as a service to the international trading community.

Dated: May 18, 2015.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2015–13106 Filed 5–29–15; 8:45 am]

BILLING CODE 3510–DS–P

[2] *See also* the Enforcement and Compliance Web site at *http://trade.gov/enforcement/.*

[3] In accordance with 19 CFR 351.213(b)(1), parties should specify that they are requesting a review of entries from exporters comprising the entity, and to the extent possible, include the names of such exporters in their request.

[4] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

New England Fishery Management Council (NEFMC); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) will hold a three-day meeting to consider actions affecting New England fisheries in the exclusive economic zone (EEZ).

DATES: The meeting will be held on Tuesday, Wednesday and Thursday, starting at 8:30 a.m. on each of the meeting days.

ADDRESSES: The meeting will be held at the Hotel Viking, 1 Bellevue Ave., Newport, RI 02840. The telephone number is (401) 847–3300. Check *www.hotelviking.com/* for online information.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950; telephone: (978) 465–0492.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Tuesday, June 16, 2015

The Council meeting will begin with introductions followed by brief reports from the NEFMC Chairman and Executive Director, the NOAA Fisheries Regional Administrator (Greater Atlantic Region), the Northeast Fisheries Science Center and Mid-Atlantic Fishery Management Council liaisons, NOAA General Counsel and Office of Law Enforcement, and representatives of the Atlantic States Marine Fisheries Commission and U.S Coast Guard. The public will then have an opportunity to bring forward brief comments on items that are relevant to Council business but otherwise not listed on the published agenda. The NEFMC also will finalize its comments on a proposed rule to revise the guidelines for National Standards 1, 3, and 7 of the Magnuson-Stevens Fishery Conservation and Management Act. Prior to a lunch break, Council members will receive a report from its Habitat Committee. The intent is to finalize the management measures that remain outstanding from the April 2015 Council meeting by approving them for inclusion in Omnibus Essential Fish Habitat Amendment 2. Specifically, the Council will select Georges Bank habitat management areas and mortality alternatives, as well as spawning alternatives for Georges Bank/Southern New England and the Gulf of Maine, and then approve the entire amendment for submission to NMFS. Discussion about this agenda item will continue after the lunch break and until the meeting adjourns at the end of this meeting day.

Wednesday, June 17, 2015

The Wednesday session will begin with a report on the April 2015 Atlantic herring operational stock assessment. This will be followed by a review of topics and issues related to the development of Amendment 8 to the Atlantic Herring Fishery Management Plan (FMP). They include consideration of the following: (1) A report from the Ecosystem-based Fisheries Management (EBFM) Plan Development Team about the development of alternatives for a herring acceptable biological catch (ABC) control rule that includes consideration of the role of herring as a forage species in the ecosystem; (2) a report from the Council's Scientific and Statistical Committee (SSC) on the development of an ecosystem-based ABC control rule for Atlantic herring; (3) recommendations from the Joint Herring/EBFM Committee; and (4) the Amendment 8 scoping comments. The Council will then provide guidance to the Herring Committee on the development of goals and objectives for Amendment 8 and ABC control rule alternatives. The SSC will report on any comments it may have on the herring stock assessment and present its recommendation for an Atlantic herring ABC to the Council.

After a noon lunch break, the Council will begin work on the Atlantic herring fishery specifications for 2016–18. They will: (1) Possibly select a preferred alternative for the 2016–18 herring ABC and take action on other elements of the herring specifications; and (2) provide guidance to the Herring Committee on developing options for Atlantic herring sub-annual catch limits; and (3) address provisions for research set-asides and river herring/shad catch caps to be included in the specifications package. The day will conclude after the Council reviews and discusses a number of reports that are scheduled to be finalized at the June meeting of the FMCs Coordination Committee. These are *Integrating NEPA Compliance into a Reauthorized Magnuson-Stevens Act, Criteria for Initiating Fisheries Allocation Reviews,* and a NOAA white paper on *Cooperative Research and Cooperative Management.*

Thursday, June 18, 2015

The Thursday session will begin with a briefing on the summary report of the March 2015 peer review of the sea scallop survey methodologies used in the Northeast. Next, the Sea Scallop Committee will discuss development of two actions associated with the Council's Sea Scallop FMP. They are Amendment 19, to address issues associated with the late implementation of fishery specifications; and Amendment 27 to the FMP, in which 2016–17 fishery specifications will be set. The Council also will approve research priorities for the 2016–17 scallop research set-aside program and discuss a draft white paper and possibly a workshop that would focus on concerns raised about scallop fishing patterns in nearshore areas. The Monkfish Committee will recommend final Council approval of Framework Adjustment 9 to the Monkfish FMP, an action that primarily involves adjustments to fishing days-at-sea in order to promote greater operational flexibility in the fishery. Following a lunch break, there will be reports from the Northeast Fisheries Science Center. The first will outline the process used to form stock assessment working groups and the second will concern the establishment of a Northeast Trawl Survey Advisory Panel. The Council's Electronic Working Group will then provide a brief update on its recent activities, followed by a Groundfish Committee report. During this last report the Council will initiate action on specifications for all groundfish stocks for fishing years 2016–18, including the three U.S./Canada stocks, for fishing year2016. It also will receive an analysis of industry costs for at-sea monitoring (ASM) and potentially discuss changes to the Northeast Multispecies FMP to address industry concerns around the feasibility of the existing requirement that sectors assume some of the costs of the ASM program.

Although other non-emergency issues not contained in this agenda may come before this Council for discussion, those issues may not be the subjects of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided that the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies (see **ADDRESSES**) at least 5 days prior to the meeting date.

Dated: May 27, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–13108 Filed 5–29–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RIN 0648–XD965]

Administrative Officers Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council (GMFMC) will host a meeting concurrently consisting of eight Regional Fishery Management Council (RFMC) Administrative Officers (AO) at the Council Coordination Committee (CCC) meeting in June 2015. The intent of this meeting is for the AO to discuss issues of relevance to the Councils, including: Performance evaluation processes and travel procedures, human resources services and Worker's Compensation process, insurance, cost principles and audit requirements.

DATES: The meeting will be held June 22–25, 2015. Registration for the meeting will begin at 2 p.m. on Monday June 22, 2015. The AO meeting will begin at 3:45 p.m. Tuesday, June 23, 2015 following the CCC Opening Remarks and updates on Budgets and the MSA Reauthorization, and recess at 5 p.m. or when business is complete. The AO meeting will reconvene at 8:30 a.m. on Wednesday, June 24, 2015 and recess at 5 p.m. or when business is complete. The AO meeting will reconvene on the final day at 8:30 a.m. on Thursday, June 25, 2015 and adjourn by 12 noon or when business is complete.

ADDRESSES:

Meeting address: The meeting will be held at the Marriott Beachside Hotel, 3841 North Roosevelt Boulevard, Key West, FL 33040; telephone: (305) 296–8100.

Council address: Gulf of Mexico Fishery Management Council, 2203 North Lois Avenue, Suite 1100, Tampa, FL 33607.

FOR FURTHER INFORMATION CONTACT: Cathy Readinger, Administrative Officer, Gulf of Mexico Fishery Management Council; telephone: (813) 348–1630; fax: (813) 348–1711; email: *cathy.readinger@gulfcouncil.org.*

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Fishery Conservation (MSA) and Management Reauthorization Act (MSRA) established the CCC by amending section 302 (16 U.S.C. 1852) of the MSA. The committee consists of the chairs, vice chairs, and executive directors of each of the eight Regional Fishery Management Councils authorized by the MSA or other Council members or staff. GMFMC will host this meeting and provide reports to the CCC for its information and discussion. All sessions are open to the public. NMFS or other Council items of discussion for each individual management committee agenda are as follows:

Agenda

Tuesday, June 23, 2015; 9:30 a.m.–3:45 p.m.; CCC Opening Session

- Welcome and Introductions
- Budget: 2016 Budget/Saltonstall-Kennedy Grants, National Observer Funding Allocation, Joint Enforcement Agreements
- MSA Reauthorization: Legislative Updates, CCC Discussion on working group report and actions

Tuesday, June 23, 2015; 3:45 p.m.–5 p.m.

- Performance Evaluation Processes
- Travel Procedures
- Webinars In Lieu of Physical Meetings
- FLSA Updates by Each Council
- Human Resource Services
- Worker's Compensation Process

—Adjourn for the day

Wednesday, June 24, 2015; 8:30 a.m.–5 p.m.

- Statement of Financial Interest Process
- Affordable Care Act and the Councils
- Post-Retirement Medical Insurance
- Uniform Administrative Requirements, Cost Principles, and Audit Requirements
- Multi-Year Budget Exercise
- Federal Student Loan Forgiveness Program
- Contracting

—Adjourn for the day

Thursday, June 25, 2015; 8:30 a.m.–12 Noon

- Actuarial Reports on Council Benefits
- Council Pay Scales
- Update of Council Benefits
- DOC/NOAA Legal Assistance

—Meeting Adjourns

The timing and order in which agenda items are addressed may change as required to effectively address the issues. The AO will meet as late as necessary to complete scheduled business.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira at the Gulf Council Office (see **ADDRESSES**), at least 5 working days prior to the meeting.

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

Dated: May 26, 2015.

Emily H. Menashes,

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

[FR Doc. 2015–13086 Filed 5–29–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RIN 0648–XD964]

Council Coordination Committee Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council (GMFMC) will host a meeting of the Council Coordination Committee (CCC) consisting of eight Regional Fishery Management Council (RFMC) chairs, vice chairs, and executive directors and its subcommittees in June 2015. The intent of this meeting is to discuss issues of relevance to the Councils, including: Budget issues, MSA reauthorization, National Standard 1, Bycatch Strategy, Presidential Task Force on Illegal, Unreported, and Unregulated (IUU) catches, NEPA, allocation working group report, Council Operational Guidelines, recreational fishery issues, habitat working group report, enforcement activities, other topics of concern to the RFMC, and decisions and follow-up activities.

DATES: The meeting will be held June 22–25, 2015. Registration for the meeting will begin at 2 p.m. on Monday June 22, 2015. The meeting will begin at 9:30 a.m. on Tuesday, June 23, 2015 and recess at 5:15 p.m. or when business is complete. The meeting will reconvene at 8:30 a.m. on Wednesday, June 24, 2015 and recess at 5:30 p.m. or when business is complete. The meeting will reconvene on the final day at 8:30

a.m. on Thursday, June 25, 2015 and adjourn by 12 noon or when business is complete.

ADDRESSES:

Meeting address: The meeting will be held at the Marriott Beachside Hotel, 3841 North Roosevelt Boulevard, Key West, FL 33040; telephone: (305) 296–8100.

Council address: Gulf of Mexico Fishery Management Council, 2203 North Lois Avenue, Suite 1100, Tampa, FL 33607.

FOR FURTHER INFORMATION CONTACT: Mr. Douglas Gregory, Executive Director, Gulf of Mexico Fishery Management Council; telephone: (813) 348–1630; fax: (813) 348–1711; email: *doug.gregory@gulfcouncil.org.*

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Fishery Conservation (MSA) and Management Reauthorization Act (MSRA) established the CCC by amending section 302 (16 U.S.C. 1852) of the MSA. The committee consists of the chairs, vice chairs, and executive directors of each of the eight Regional Fishery Management Councils authorized by the MSA or other Council members or staff. GMFMC will host this meeting and provide reports to the CCC for its information and discussion. All sessions are open to the public. NMFS or other Council items of discussion for each individual management committee agenda are as follows:

Agenda

Tuesday, June 23, 2015; 9:30 a.m.–5:15 p.m.

- Welcome and Introductions
- Budgets: 2016 Budget/Saltonstall-Kennedy Grants; National Observer Funding Allocation; Joint Enforcement Agreements
- MSA Reauthorization: Legislative Updates; CCC Discussion on working group report and actions
- National Standard 1: Individual Council Comments; Update & Approval of Draft Letter
- Bycatch Strategy

—Adjourn for the day

Wednesday, June 24, 2015; 8:30 a.m.–5:30 p.m.

- Presentations: Marine Resource Education Program; American Fisheries Society; Social Scientists in RFM Report
- Presidential Task Force on IUU
- NEPA Working Group Report: CCC White Paper; Revised MSA NEPA Procedures
- Allocation Working Group Report: CCC Guidelines; NMFS Guidelines
- Operational Guidelines
- Cooperative Research & Management
- Recreational Fishery Issues: Recreational Fishery Policy; Marine Recreational Information Program

—Adjourn for the day

Thursday, June 25, 2015; 8:30 a.m.–12 noon

- Habitat Working Group Report: Proposed 2016 Habitat Summit
- Assessment Prioritization Update
- International Affairs/Seafood Inspection
- SSC Issues: National SSC V Workshop Report; Next Meeting (location/year)
- 2016 CCC Meetings
- Other Business & Wrap-up

—Meeting Adjourns

The timing and order in which agenda items are addressed may change as required to effectively address the issues. The CCC will meet as late as necessary to complete scheduled business.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira at the Gulf Council Office (see **ADDRESSES**), at least 5 working days prior to the meeting.

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

Dated: May 26, 2015.

Emily H. Menashes,

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

[FR Doc. 2015–13087 Filed 5–29–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Monterey Bay Regional Water Project Desalination Facility; Intent To Prepare a Draft Environmental Impact Statement; Scoping Meeting

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA).

ACTION: Notice of intent to prepare environmental impact statement; Scoping meeting.

SUMMARY: An application for permit approval has been submitted by DeepWater Desal, LLC to the Monterey Bay National Marine Sanctuary (MBNMS) and California State Lands Commission (CSLC) to construct and operate a seawater reverse osmosis (SWRO) desalination facility and co-located seawater-cooled 150-megawatt computer data center campus project (Project) at Moss Landing, Monterey County, California. The permit review process will be conducted concurrently with a public process conducted pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), and the California Environmental Quality Act (CEQA). NOAA is soliciting information and comments on the range and significance of issues related to the Project proposed within MBNMS boundaries.

DATES: Comments must be received by July 1, 2015. A public meeting will be held as detailed below:

Date: Tuesday, June 16, 2015.

Location: Moss Landing Marine Laboratories (MLML), Main Building Conference Room.

Address: 8272 Moss Landing Road, Moss Landing, CA 95039.

Times: sessions begin at 2:00 p.m. and at 6:00 p.m.

ADDRESSES: Comments may be submitted by either of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NOS-2015-0069*, click the ''Comment Now!'' icon, complete the required fields and enter or attach your comments.
- *Mail:* MBNMS Desalination Project Lead, 99 Pacific Ave, BLDG 455a, Monterey, CA 93940

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NOAA. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. ONMS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Bridget Hoover at 99 Pacific Ave, BLDG 455a, Monterey, CA 93940 or *mbnms.comments@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background Information

I. Background

An application for permit approval has been submitted by DeepWater Desal,

LLC to construct and operate a seawater reverse osmosis (SWRO) desalination facility capable of producing 25,000 acre-feet per year (AFY) of potable water and a co-located seawater-cooled computer data center campus on a 110-acre site located approximately 1.5 miles east of Moss Landing. Seawater intake and brine discharge pipelines would extend west from Moss Landing Harbor to the upper reaches of the submarine Monterey Canyon and the north shelf, respectively, Monterey Bay National Marine Sanctuary (MBNMS).

II. Need for action

This notice of intent (NOI) to prepare a draft environmental impact statement and conduct scoping is published in accordance with: the California Environmental Quality Act (CEQA); California Public Resources Code section 21080.4, subdivision (a); State CEQA Guidelines section 15082; section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, as amended; and the White House Council on Environmental Quality Regulations for Implementing the Procedural Provisions of NEPA (CEQ NEPA Regulations).

The California State Lands Commission (CSLC) and MBNMS, as CEQA and NEPA lead agencies respectively, will prepare a joint Environmental Impact Report/Environmental Impact Statement (EIR/EIS) to identify and assess potential environmental impacts associated with the proposed DeepWater Desal, LLC Monterey Bay Regional Water Project (Project). Agencies would use the EIR/EIS to consider related permits or other approvals for the Project as proposed. Possible alternatives could include not approving the Project or approving the Project with additional modifications identified as part of the terms and conditions of a permit or other approval.

Publication of this notice initiates the public scoping process to solicit public and agency comment, in writing or at the public meeting, regarding the full spectrum of environmental issues and concerns relating to the scope and content of the EIR/EIS, including:

- Analyses of the human and marine resources that could be affected;
- the nature and extent of the potential significant impacts on those resources;
- a reasonable range of alternatives to the proposed action; and
- mitigation measures.

III. Process

This NOI is published in conjunction with the CSLC NOI, as this is a joint process between NOAA/MBNMS, the lead federal agency, and the CSLC, the lead state agency. The two agencies will prepare a joint Environmental Impact Report/Environmental Impact Statement (EIR/EIS), and will hold a joint public scoping meeting for the project on Tuesday, June 16, 2015; Sessions begin at 2:00 pm and 6:00 pm, at Moss Landing Marine Laboratories at 8272 Moss Landing Road, CA 95039.

IV. Federal Consultations

This notice also advises the public that NOAA will coordinate its consultation responsibilities under section 7 of the Endangered Species Act (ESA), Essential Fish Habitat (EFH) under the Magnuson Stevens Fishery Conservation and Management Act (MSA), section 106 of the National Historic Preservation Act (NHPA, 16 U.S.C. 470), and Federal Consistency review under the Coastal Zone Management Act (CZMA), along with its ongoing NEPA process including the use of NEPA documents and public and stakeholder meetings to also meet the requirements of other federal laws.

In fulfilling its consultation responsibility under the ESA, MSA, NHPA, CZMA and NEPA, NOAA intends to identify consulting parties and involve the public in accordance with NOAA's NEPA procedures, and develop in consultation with identified consulting parties alternatives and proposed measures that might avoid, minimize or mitigate any adverse effects on endangered species, essential fish habitat, historic properties, or coastal zone management issues, and describe them in any environmental assessment or draft environmental impact statement.

Authority: 16 U.S.C. 1431 *et seq.*

Dated: May 21, 2015.

John Armor,

Acting Director for the Office of National Marine Sanctuaries.

[FR Doc. 2015–12877 Filed 5–29–15; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Mid-Atlantic Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's (MAFMC) Summer Flounder, Scup, and Black Sea Bass Advisory Panel (AP) will hold a public meeting.

DATES: The meeting will be held on Wednesday June 17, 2015 from 10 a.m. to 4 p.m. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held at the Double Tree by Hilton Baltimore—BWI Airport, 890 Elkridge Landing Road, Linthicum, MD 21090; telephone: (410) 859–8400.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The MAFMC's Summer Flounder, Scup, and Black Sea Bass Advisory Panel (AP) will meet jointly with the Atlantic States Marine Fisheries Commission's (ASMFC) Summer Flounder, Scup, and Black Sea Bass Advisory Panels. The purpose of this meeting is to discuss recent performance of the commercial and recreational fisheries for summer flounder, scup, and black sea bass. Council staff will work with the AP to write 2015 Fishery Performance Reports. The MAFMC and the ASMFC will consider the Fishery Performance Reports in August when setting fishery specifications (*i.e.* catch and landings limits and management measures) for 2016–18.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: May 26, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–13056 Filed 5–29–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the

Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Socioeconomics of Commercial Whale Watching Observation Operations in the Channel Islands National Marine Sanctuary.

OMB Control Number: 0648–xxxx.

Form Number(s): None.

Type of Request: Regular (request for a new information collection).

Number of Respondents: 21.

Average Hours per Response: One hour and 30 minutes to compile information; one hour for interview.

Burden Hours: 53.

Needs and Uses: This request is for a new information collection.

This is a survey of commercial whale watching operations that operate in and around the current Channel Islands National Marine Sanctuary (CINMS). Information will be obtained to assess the value of the whale watching industry to the local economy, as well as the potential socioeconomic costs or benefits from alternative management options proposed by the CINMS Marine Shipping Working Group to reduce negative encounters between vessels and whales.

Affected Public: Business and other for-profit organizations.

Frequency: One time.

Respondent's Obligation: Voluntary.

This information collection request may be viewed at *reginfo.gov*. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: May 27, 2015.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2015–13095 Filed 5–29–15; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Idaho National Laboratory

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Idaho National Laboratory. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Tuesday, June 23, 2015, 8:00 a.m.–3:00 p.m. The opportunity for public comment is at 2:15 p.m. This time is subject to change; please contact the Federal Coordinator (below) for confirmation of times prior to the meeting.

ADDRESSES: Hilton Garden Inn, 700 Lindsay Blvd., Idaho Falls, ID 83402.

FOR FURTHER INFORMATION CONTACT: Robert L. Pence, Federal Coordinator, Department of Energy, Idaho Operations Office, 1955 Fremont Avenue, MS–1203, Idaho Falls, Idaho 83415. Phone (208) 526–6518; Fax (208) 526–8789 or email: *pencerl@id.doe.gov* or visit the Board's Internet home page at: *http://inlcab.energy.gov/*.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Topics (agenda topics may change up to the day of the meeting; please contact Robert L. Pence for the most current agenda):

- Welcome and Opening Remarks
- Agency Update Presentations
- Public Comment

Public Participation: The EM SSAB, Idaho National Laboratory, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Robert L. Pence at least seven days in advance of the meeting at the phone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral presentations pertaining to agenda items should contact Robert L. Pence at the address or telephone number listed above. The request must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Robert L. Pence, Federal Coordinator, at the address and phone number listed above. Minutes will also be available at the following Web site: *http://inlcab.energy.gov/pages/meetings.php.*

Issued at Washington, DC on May 22, 2015.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2015–13125 Filed 5–29–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

[Docket No. EERE–2015–BT–BC–0002]

DOE Proposals for the 2018 International Energy Conservation Code (IECC)

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

ACTION: Notice of availability; webinar and public meeting.

SUMMARY: The U.S. Department of Energy (DOE) participates in the public process administered by the International Code Council (ICC), which produces the International Energy Conservation Code (IECC). DOE published a notice in the **Federal Register** on April 14, 2015 outlining the process by which the Department will participate in the development of the 2018 IECC. This notice builds upon the previous notice in identifying several events surrounding development of DOE proposals for the 2018 IECC, including the availability of draft proposals and supporting analysis, as well as upcoming stakeholder meetings.

DATES: DOE will host the following events:

- Webinar: Introduction of initial DOE Concepts under consideration for the 2018 IECC:

Date: Thursday, May 28, 2015

- Stakeholder Meeting: Public meeting for interested parties to present their concepts for the 2018 IECC, and to encourage an exchange of ideas amongst stakeholders:

Date: June 15–16, 2015

Location: Denver, Colorado

ADDRESSES: Advanced registration is required for both the webinar and stakeholder meeting. For more information on registering, please see the **SUPPLEMENTARY INFORMATION** section of this notice. The stakeholder meetings will be held at the Crowne Plaza Denver Downtown, 1450 Glenarm Place, Denver, Colorado 80202.

Interested parties are invited to submit comments on DOE proposals for

the IECC. Any comments submitted must reference the Notice for DOE Proposals for the 2018 International Energy Conservation Code (IECC), docket number EERE–2015–BT–BC–0002. Comments may be submitted by using either of the following methods:

1. *Federal eRulemaking Portal: http://www.regulations.gov/#!docketDetail;D=EERE-2015-BT-BC-0002.* Follow the instructions for submitting comments.

2. *Email: IECC2015BC0002@ee.doe.gov.* Include EERE–2015–BT–BC–0002 in the subject line of the message.

Instructions: All submissions received must include the agency name (U.S. DOE), docket number (EERE–2015–BT–BC–0002), and applicable DOE proposal ID numbers (see **SUPPLEMENTARY INFORMATION** section of this notice for additional instructions).

FOR FURTHER INFORMATION CONTACT: Jeremiah Williams; U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW., Washington, DC 20585; Telephone: (202) 287–1941; Email: *jeremiah.williams@ee.doe.gov.*

For legal issues: Kavita Vaidyanathan; U.S. Department of Energy, Office of the General Counsel, Forrestal Building, GC–33, 1000 Independence Avenue SW., Washington, DC 20585; Telephone: (202) 586–0669; Email: *kavita.vaidyanathan@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The U.S. Department of Energy (DOE) participates in the public process administered by the International Code Council (ICC) which produces the International Energy Conservation Code (IECC). As a participant in this process, the Department considers and evaluates concepts it is considering submitting as proposed changes to the IECC. DOE published a notice in the **Federal Register** on April 14, 2015, outlining the process by which the Department will participate in the development of the 2018 IECC (80 FR 19972). DOE has published its initial concepts at the DOE Building Energy Codes Program Web site and has scheduled several events to discuss 2018 IECC development.

Availability of DOE Proposals for the 2018 IECC

The Department will continue to publish its proposals and supporting information as it becomes available over the coming months. As information will be updated continually, interested parties are urged to monitor the DOE Building Energy Codes Program Web site and associated stakeholder mailing lists:

- DOE Proposal Web page: *www.energycodes.gov/development/2018IECC.*
- Stakeholder Updates: *http://www.energycodes.gov/news.*

Submitting Comments on DOE Proposals for the IECC

Interested parties are invited to submit comments on DOE proposals by email or public docket, as outlined in the **ADDRESSES** section of this notice. Comments will be accepted beginning immediately upon publication of this notice, and ongoing through later this year. To allow adequate time to prepare and publish final proposals, the Department will specify a comment deadline on the DOE Proposal Web page. Further instructions for submitting comments on DOE proposals, including identifiers (*e.g.,* DOE proposal numbers) and associated deadlines, are provided on the above DOE Proposal Web page. All DOE proposals and supporting information will be made available to the general public prior to submission to the ICC.

Webinar and Stakeholder Meeting

The Department will host a webinar to present its initial concepts for the 2018 IECC. During the webinar, DOE will present an overview of each concept under consideration for a potential code change proposal. In addition, the Department will convene a public meeting during which stakeholders can present their concepts for the 2018 IECC. As part of these meetings, DOE will also present its own concepts. The goal of the meetings will be to encourage communication amongst stakeholders. These events are scheduled as follows:

Webinar: Introduction of initial DOE concepts under consideration for the 2018 IECC: Thursday, May 28, 2015.

- *Commercial Session:* 1:00–2:30 p.m. (EDT).

Registration: https://attendee.gotowebinar.com/register/5677147236967231233.

- *Residential Session:* 3:30–5:00 p.m. (EDT).

Registration: *https://attendee.gotowebinar.com/register/3937419675150886145.*

Stakeholder Meeting: Public meeting for interested parties to present their concepts for the 2018 IECC.

Location: Crowne Plaza Denver Downtown, 1450 Glenarm Place, Denver, CO 80202.

- *Residential Session:* Monday, June 15th from 1:00–5:00 p.m. (MDT).
- *Commercial Session:* Tuesday, June 16th from 8:00 a.m.–2:00 p.m. (MDT).

(**Note:** If residential requests for presentation time exceed commercial requests, the residential session may continue on Tuesday morning at 8:00 a.m. MDT.)

Advanced registration is required for the webinar and stakeholder meeting—please register early so that time may be allotted for stakeholder presentations. DOE will both moderate and participate in these events.

More information on the Department's support for building energy codes, including participation in the development of model codes, is available on the DOE Building Energy Codes Program Web site, *www.energycodes.gov.*

Issued in Washington, DC, on May 21, 2015.

Roland Risser,

Director, Building Technologies Office, Energy Efficiency & Renewable Energy.

[FR Doc. 2015–13103 Filed 5–29–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings—2

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings in Existing Proceedings

Docket Numbers: RP15–594–000.
Applicants: KPC Pipeline, LLC.
Description: Additional information requested in paragraph 11 of April 21, 2015 Order of KPC Pipeline, LLC.
Filed Date: 5/1/15.
Accession Number: 20150501–5479.
Comments Due: 5 p.m. ET 6/1/15.

Docket Numbers: RP15–594–000.
Applicants: KPC Pipeline, LLC.
Description: Supplement [Excel spreadsheet] to May 1, 2015 Additional information requested in paragraph 11 of April 21, 2015 Order of KPC Pipeline, LLC.
Filed Date: 5/5/15.
Accession Number: 20150505–5237.
Comments Due: 5 p.m. ET 6/1/15.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

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 5:00 p.m. Eastern time on the specified comment date.

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 May 20, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–13078 Filed 5–29–15; 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 corporate filings:

Docket Numbers: EC15–145–000.

Applicants: Lost Creek Wind, LLC.

Description: Application for Authorization of Transaction Under Section 203 of the Federal Power Act, Requests for Expedited Action, Waivers of Filing Requirements and Confidential Treatment of Transaction Documents of Lost Creek Wind, LLC, et al.

Filed Date: 5/22/15.

Accession Number: 20150522–5321.

Comments Due: 5 p.m. ET 6/12/15.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1325–002; ER10–1946–002; ER14–2323–000; ER11–2080–002; ER10–1333–002; ER14–2319–000; ER12–1958–002; ER14–2321–000; ER10–1335–002.

Applicants: CinCap V LLC, Duke Energy Beckjord, LLC, Duke Energy Commercial Asset Management, Inc., Duke Energy Commercial Enterprises, Inc., Duke Energy Piketon, LLC, Duke Energy Retail Sales, LLC.

Description: Additional information related to June 30, 2014 Triennial Market Power Analysis Update for the Southeast Region of Duke Energy Corporation MBR Sellers.

Filed Date: 5/21/15.

Accession Number: 20150521–5250.

Comments Due: 5 p.m. ET 6/11/15.

Docket Numbers: ER15–1222–002.

Applicants: Southern California Edison Company.

Description: Tariff Amendment per 35.17(b): Amended GIA and Distrib Serv Agmt re Edom Hills Wind Park Project to be effective 12/31/9998.

Filed Date: 5/22/15.

Accession Number: 20150522–5009.

Comments Due: 5 p.m. ET 6/12/15.

Docket Numbers: ER15–1365–001.

Applicants: Morris Cogeneration, LLC.

Description: Tariff Amendment per 35.17(b): Response to Deficiency Letter to be effective 5/1/2015.

Filed Date: 5/22/15.

Accession Number: 20150522–5006.

Comments Due: 5 p.m. ET 6/12/15.

Docket Numbers: ER15–1406–001.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Tariff Amendment per 35.17(b): 2015–05–22_SA 2766 Amendment to ATC-City of Elkhorn CFA to be effective 5/31/2015.

Filed Date: 5/22/15.

Accession Number: 20150522–5067.

Comments Due: 5 p.m. ET 6/12/15.

Docket Numbers: ER15–1407–001.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Tariff Amendment per 35.17(b): 2015–05–22_SA 2767 Amendment to ATC-Manitowoc Public Utilities CFA to be effective 5/31/2015.

Filed Date: 5/22/15.

Accession Number: 20150522–5068.

Comments Due: 5 p.m. ET 6/12/15.

Docket Numbers: ER15–1409–001.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Tariff Amendment per 35.17(b): 2015–05–22_SA 2769 Amendment to ATC-City of Reedsburg CFA to be effective 5/31/2015.

Filed Date: 5/22/15.

Accession Number: 20150522–5081.

Comments Due: 5 p.m. ET 6/12/15.

Docket Numbers: ER15–1411–001.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Tariff Amendment per 35.17(b): 2015–05–22_SA 2770 Amendment to ATC-City of Sun Prairie CFA to be effective 5/31/2015.

Filed Date: 5/22/15.

Accession Number: 20150522–5103.

Comments Due: 5 p.m. ET 6/12/15.

Docket Numbers: ER15–1473–001.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Tariff Amendment per 35.17(b): 2015–05–22_SA 2771 Amendment to ATC-Cloverland CFA to be effective 6/8/2015.

Filed Date: 5/22/15.

Accession Number: 20150522–5104.

Comments Due: 5 p.m. ET 6/12/15.

Docket Numbers: ER15–1479–001.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Tariff Amendment per 35.17(b): 2015–05–22_SA 2773 Amendment to ATC-Adams Columbia CFA to be effective 6/9/2015.

Filed Date: 5/22/15.

Accession Number: 20150522–5105.

Comments Due: 5 p.m. ET 6/12/15.

Docket Numbers: ER15–1481–001.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Tariff Amendment per 35.17(b): 2015–05–22_SA 2776 Amendment to ATC-Village of Prairie du Sac CFA to be effective 6/9/2015.

Filed Date: 5/22/15.

Accession Number: 20150522–5142.

Comments Due: 5 p.m. ET 6/12/15.

Docket Numbers: ER15–1482–001.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Tariff Amendment per 35.17(b): 2015–05–22_SA 2777 Amendment to ATC-City of Wisconsin Rapids CFA to be effective 6/9/2015.

Filed Date: 5/22/15.

Accession Number: 20150522–5144.

Comments Due: 5 p.m. ET 6/12/15.

Docket Numbers: ER15–1483–001.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Tariff Amendment per 35.17(b): 2015–05–22_SA 2775 Amendment to ATC-Marshfield Electric CFA to be effective 6/9/2015.

Filed Date: 5/22/15.

Accession Number: 20150522–5140.

Comments Due: 5 p.m. ET 6/12/15.

Docket Numbers: ER15–1630–001.

Applicants: US Borax, Inc.

Description: Tariff Amendment per 35.17(b): Supplement to MBRA to be effective 6/30/2015.

Filed Date: 5/22/15.

Accession Number: 20150522–5107.

Comments Due: 5 p.m. ET 6/12/15.

Docket Numbers: ER15–1767–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Request for One-Time Waiver of Certain Tariff Provisions of Midcontinent Independent System Operator, Inc.

Filed Date: 5/21/15.

Accession Number: 20150521–5245.

Comments Due: 5 p.m. ET 6/11/15.

Docket Numbers: ER15–1768–000.

Applicants: ISO New England Inc.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): Conforming Filing for Tariff Section III.10, Record ID No. 138 to be effective 6/1/2015.

Filed Date: 5/22/15.

Accession Number: 20150522–5101.

Comments Due: 5 p.m. ET 6/12/15.

Docket Numbers: ER15–1769–000.

Applicants: DPL Energy Resources, Inc.

Description: Notice of Cancellation of Market Based Rate Tariff Rate Schedule No. 1 of DPL Energy Resources, Inc.

Filed Date: 5/22/15.

Accession Number: 20150522–5202.

Comments Due: 5 p.m. ET 6/12/15.

Docket Numbers: ER15–1770–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): PJM submits revisions to OA Schedule 12 to remove Intergrid Mideast Group, LLC to be effective 12/31/9998.
Filed Date: 5/22/15.
Accession Number: 20150522–5204.
Comments Due: 5 p.m. ET 6/12/15.
Docket Numbers: ER15–1771–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2015–05–22 Mississippi LRZ Filing to be effective 7/22/2015.
Filed Date: 5/22/15.
Accession Number: 20150522–5267.
Comments Due: 5 p.m. ET 6/12/15.
Docket Numbers: ER15–1772–000.
Applicants: Interstate Power and Light Company.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): Interstate Power and Light Company Wholesale Power Supply Agreement to be effective 12/31/9998.
Filed Date: 5/22/15.
Accession Number: 20150522–5270.
Comments Due: 5 p.m. ET 6/12/15.
Docket Numbers: ER15–1775–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): Basin Electric Power Cooperative Formula Rate to be effective 10/1/2015.
Filed Date: 5/22/15.
Accession Number: 20150522–5358.
Comments Due: 5 p.m. ET 6/12/15.

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 5:00 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: May 22, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–13076 Filed 5–29–15; 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: RP15–993–000.
Applicants: PGPipeline LLC.
Description: Compliance filing per 154.203: Order No. 801 Compliance Filing to be effective 7/1/2015.
Filed Date: 5/19/15.
Accession Number: 20150519–5106.
Comments Due: 5 p.m. ET 6/1/15.
Docket Numbers: RP15–994–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) rate filing per 154.204: Cap Rel Neg Rate Agmt (Oglethorpe 8482 to Sequent 44523) to be effective 5/1/2015.
Filed Date: 5/19/15.
Accession Number: 20150519–5107.
Comments Due: 5 p.m. ET 6/1/15.
Docket Numbers: RP15–995–000.
Applicants: Equitrans, L.P.
Description: § 4(d) rate filing per 154.204: Neogotiated Capacity Release Agreement—5/19/2015 to be effective 5/19/2015.
Filed Date: 5/19/15.
Accession Number: 20150519–5113.
Comments Due: 5 p.m. ET 6/1/15.

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 5:00 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: RP15–210–001.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description: Compliance filing per 154.203: Cashout Report and Refund Plan 2013–2014—Revised Appendix C.
Filed Date: 5/19/15.
Accession Number: 20150519–5116.
Comments Due: 5 p.m. ET 6/1/15.

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 5:00 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, 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: May 20, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–13074 Filed 5–29–15; 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 corporate filings:

Docket Numbers: EC15–146–000.
Applicants: NRG Yield Operating LLC, Desert Sunlight 250, LLC, Desert Sunlight 300, LLC.
Description: Joint Application for Approval under Section 203 of the Federal Power Act and Request for Expedited Approval of NRG Yield Operating LLC, et al.
Filed Date: 5/22/15.
Accession Number: 20150522–5471.
Comments Due: 5 p.m. ET 6/12/15.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1484–010.
Applicants: Shell Energy North America (US), L.P.
Description: Supplement to December 29, 2014 Updated Market Power Analysis for the Southeast Region of Shell Energy North America (US), L.P.
Filed Date: 5/26/15.
Accession Number: 20150526–5150.
Comments Due: 5 p.m. ET 6/9/15.
Docket Numbers: ER13–1936–001.
Applicants: PJM Interconnection, L.L.C.
Description: Compliance filing per 35: Compliance Filing per 1/23/15 Order in Docket No. ER13–1936 to be effective 1/1/2015.
Filed Date: 5/26/15.
Accession Number: 20150526–5181.
Comments Due: 5 p.m. ET 6/16/15.
Docket Numbers: ER15–1456–001.
Applicants: Beaver Falls, L.L.C.
Description: Tariff Amendment per 35.17(b): Amended Notice of Succession to be effective 3/6/2015.
Filed Date: 5/26/15.
Accession Number: 20150526–5157.
Comments Due: 5 p.m. ET 6/16/15.

Docket Numbers: ER15–1457–001.
Applicants: Syracuse, L.L.C.
Description: Tariff Amendment per 35.17(b): Amended Notice of Succession to be effective 3/6/2015.
Filed Date: 5/26/15.
Accession Number: 20150526–5164.
Comments Due: 5 p.m. ET 6/16/15.
Docket Numbers: ER15–1543–001.
Applicants: Wisconsin Public Service Corporation.
Description: Tariff Amendment per 35.17(b): Revised Local Balancing Authority Area Agreement Between WPSC an to be effective 7/25/2015.
Filed Date: 5/26/15.
Accession Number: 20150526–5160.
Comments Due: 5 p.m. ET 6/16/15.
Docket Numbers: ER15–1776–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2015–05–22 Pricing under Emergency to be effective 12/31/9998.
Filed Date: 5/22/15.
Accession Number: 20150522–5376.
Comments Due: 5 p.m. ET 6/12/15.
Docket Numbers: ER15–1777–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): Heartland Consumers Power District Formula Rate to be effective 10/1/2015.
Filed Date: 5/22/15.
Accession Number: 20150522–5377.
Comments Due: 5 p.m. ET 6/12/15.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES15–30–000.
Applicants: The United Illuminating Company.
Description: Supplemental Exhibits to May 8, 2015 Application requesting authorization to issue short-term debt securities in an amount not to exceed $400 million of The United Illuminating Company.
Filed Date: 5/22/15.
Accession Number: 20150522–5117.
Comments Due: 5 p.m. ET 6/1/15.

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 5:00 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: May 26, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–13077 Filed 5–29–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR15–26–000]

NuStar Logistics, L.P.; Notice of Petition for Declaratory Order

Take notice that on May 22, 2015, pursuant to Rule 207(a)(2) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207(a)(2) (2014), NuStar Logistics, L.P. (''NuStar'') filed a petition for a declaratory order seeking a declaratory order concerning NuStar's supplemental open season held for its South Texas Crude Oil Pipeline System Expansion Project (''Expansion Project''). The Expansion Project involves an expansion of NuStar's existing pipeline system that transports crude oil from various points in the Eagle Ford shale region of South Texas to NuStar's Corpus Christi North Beach Terminal in Nueces County, Texas, all as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

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 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern time on June 22, 2015.

Dated: May 26, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–13090 Filed 5–29–15; 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 corporate filings:

Docket Numbers: EC15–144–000.
Applicants: Rising Tree Wind Farm III LLC, Arbuckle Mountain Wind Farm LLC.
Description: Application for Authorization for Disposition of Jurisdictional Facilities and Request for Expedited Action of Rising Tree Wind Farm III LLC, et. al.
Filed Date: 5/21/15.
Accession Number: 20150521–5190.
Comments Due: 5 p.m. ET 6/11/15.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG15–89–000.
Applicants: Greenleaf Power Management LLC.
Description: Self-Certification as an EWG of Greenleaf Power Management LLC.
Filed Date: 5/20/15.
Accession Number: 20150520–5219.
Comments Due: 5 p.m. ET 6/10/15.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER13–1940–004.
Applicants: Ohio Valley Electric Corporation.
Description: Compliance filing per 35: Interregional Refile to be effective 1/1/2015.

Filed Date: 5/20/15.
Accession Number: 20150520–5213.
Comments Due: 5 p.m. ET 6/8/15.
Docket Numbers: ER15–1016–000.
Applicants: Shafter Solar, LLC.
Description: Second Amendment to February 9, 2015 and March 24, 2015 Shafter Solar, LLC tariff filings.
Filed Date: 5/21/15.
Accession Number: 20150521–5095.
Comments Due: 5 p.m. ET 6/11/15.
Docket Numbers: ER15–1222–001.
Applicants: Southern California Edison Company.
Description: Tariff Amendment per 35.17(b): SCE's Response to Deficiency re Unexecuted Edom Hills GIA & Distrib Serv Agmt to be effective 9/30/2015.
Filed Date: 5/21/15.
Accession Number: 20150521–5111.
Comments Due: 5 p.m. ET 6/11/15.
Docket Numbers: ER15–1375–000.
Applicants: McCoy Solar, LLC.
Description: Amendment to March 25, 2015 McCoy Solar, LLC tariff filing.
Filed Date: 5/21/15.
Accession Number: 20150521–5103.
Comments Due: 5 p.m. ET 6/11/15.
Docket Numbers: ER15–1392–001.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Tariff Amendment per 35.17(b): 2015–05–21_Montezuma-Tipton Att O Amendment to be effective 6/1/2015.
Filed Date: 5/21/15.
Accession Number: 20150521–5124.
Comments Due: 5 p.m. ET 6/11/15.
Docket Numbers: ER15–1418–000.
Applicants: Adelanto Solar II, LLC.
Description: Amendment to March 31, 2015 Adelanto Solar II, LLC tariff filing.
Filed Date: 5/21/15.
Accession Number: 20150521–5150.
Comments Due: 5 p.m. ET 6/11/15.
Docket Numbers: ER15–1665–000.
Applicants: Greenleaf Power Management LLC.
Description: Supplement to May 4, 2015 Greenleaf Power Management LLC tariff filing.
Filed Date: 5/20/15.
Accession Number: 20150520–5266.
Comments Due: 5 p.m. ET 6/10/15.
Docket Numbers: ER15–1757–000.
Applicants: New York Independent System Operator, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): NYISO 205 filing Executed Non-Conforming Interconnection Facilities Study Agrmnt to be effective 4/23/2015.
Filed Date: 5/20/15.
Accession Number: 20150520–5214.
Comments Due: 5 p.m. ET 6/10/15.
Docket Numbers: ER15–1758–000.
Applicants: Southern California Edison Company.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): Filing of LGIA for RE Garland Project to be effective 5/21/2015.
Filed Date: 5/21/15.
Accession Number: 20150521–5001.
Comments Due: 5 p.m. ET 6/11/15.
Docket Numbers: ER15–1759–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2015–05–21_SA 2789 ATC–ITC Midwest Operating Agreement to be effective 7/21/2015.
Filed Date: 5/21/15.
Accession Number: 20150521–5082.
Comments Due: 5 p.m. ET 6/11/15.
Docket Numbers: ER15–1760–000.
Applicants: Southwestern Public Service Company.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2015–5–21_SPS–RWSE–E&P–680–0.0.0-Filing to be effective 7/20/2015.
Filed Date: 5/21/15.
Accession Number: 20150521–5096.
Comments Due: 5 p.m. ET 6/11/15.
Docket Numbers: ER15–1761–000.
Applicants: Southwestern Public Service Company.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2015–5–21_SPS-ChvCtySlr-E&P–681–0.0.0-Filing to be effective 7/20/2015.
Filed Date: 5/21/15.
Accession Number: 20150521–5101.
Comments Due: 5 p.m. ET 6/11/15.
Docket Numbers: ER15–1762–000.
Applicants: Southwestern Public Service Company.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2015–5–21_SPS-OrWR–E&P–682–0.0.0-Filing to be effective 7/20/2015.
Filed Date: 5/21/15.
Accession Number: 20150521–5105.
Comments Due: 5 p.m. ET 6/11/15.
Docket Numbers: ER15–1763–000.
Applicants: El Paso Electric Company.
Description: Notice of Cancellation of Rate Schedule 53 of El Paso Electric Company.
Filed Date: 5/21/15.
Accession Number: 20150521–5108.
Comments Due: 5 p.m. ET 6/11/15.
Docket Numbers: ER15–1764–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2015–05–21_SA 2789 Notice of Termination ATC–ITCM Operating Agreement to be effective 7/21/2015.
Filed Date: 5/21/15.
Accession Number: 20150521–5133.
Comments Due: 5 p.m. ET 6/11/15.
Docket Numbers: ER15–1765–000.
Applicants: California Independent System Operator Corporation.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2015–05–21 APS ABAOA and Termination of RS 17 to be effective 5/22/2015.
Filed Date: 5/21/15.
Accession Number: 20150521–5135.
Comments Due: 5 p.m. ET 6/11/15.
Docket Numbers: ER15–1765–001.
Applicants: California Independent System Operator Corporation.
Description: Tariff Amendment per 35.17(b): 2015–05–21 Amended APS ABAOA to be effective 7/23/2015.
Filed Date: 5/21/15.
Accession Number: 20150521–5147.
Comments Due: 5 p.m. ET 6/11/15.
Docket Numbers: ER15–1766–000.
Applicants: PJM Interconnection, L.L.C., The Dayton Power and Light Company.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): DP&L submits Original Service Agreement No. 4124 to be effective 5/22/2015.
Filed Date: 5/21/15.
Accession Number: 20150521–5176.
Comments Due: 5 p.m. ET 6/11/15.

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 5:00 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: May 21, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–13075 Filed 5–29–15; 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: RP15–984–000.
Applicants: White River Hub, LLC.
Description: Annual Report of Fuel Gas Reimbursement Percentage for 2015 of White River Hub, LLC.
Filed Date: 5/12/15.
Accession Number: 20150512–5094.
Comments Due: 5 p.m. ET 5/26/15.

Docket Numbers: RP15–985–000.
Applicants: Questar Southern Trails Pipeline Company.
Description: Annual Report of Fuel Gas Reimbursement Percentage for 2015 of Questar Southern Trails Pipeline Company.
Filed Date: 5/12/15.
Accession Number: 20150512–5097.
Comments Due: 5 p.m. ET 5/26/15.

Docket Numbers: RP15–996–000.
Applicants: Gulf South Pipeline Company, LP.
Description: Section 4(d) rate filing per 154.204: Cap Rel Neg Rate Agmts (Atlanta Gas 8438 to various eff 5/1/15) to be effective 5/1/2015.
Filed Date: 5/21/15.
Accession Number: 20150521–5066.
Comments Due: 5 p.m. ET 6/2/15.

Docket Numbers: RP15–997–000.
Applicants: Natural Gas Pipeline Company of America.
Description: Section 4(d) rate filing per 154.204: Substitute Published Index Prices to be effective 7/1/2015.
Filed Date: 5/21/15.
Accession Number: 20150521–5224.
Comments Due: 5 p.m. ET 6/2/15.

Docket Numbers: RP15–998–000.
Applicants: Texas Eastern Transmission, LP.
Description: Section 4(d) rate filing per 154.204: Negotiated Rate—Chevron Jun2014 TEAM2014 Release to be effective 6/1/2015.
Filed Date: 5/22/15.
Accession Number: 20150522–5143.
Comments Due: 5 p.m. ET 6/3/15.

Docket Numbers: RP15–999–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: Section 4(d) rate filing per 154.204: Negotiated Rates Cleanup—Contract 789456 to be effective 6/1/2015.
Filed Date: 5/22/15.
Accession Number: 20150522–5147.
Comments Due: 5 p.m. ET 6/3/15.

Docket Numbers: RP15–1000–000.
Applicants: Rockies Express Pipeline LLC.
Description: Section 4(d) rate filing per 154.204: Neg Rate 2015–05–15 E2W to be effective 7/1/2015.
Filed Date: 5/22/15.
Accession Number: 20150522–5234.
Comments Due: 5 p.m. ET 6/3/15.

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 5:00 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: RP15–956–001.
Applicants: Gulf South Pipeline Company, LP.
Description: Tariff Amendment per 154.205(b): Amendment to Filing in RP15–956–000 to be effective 5/1/2015.
Filed Date: 5/20/15.
Accession Number: 20150520–5112.
Comments Due: 5 p.m. ET 6/1/15.

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 5:00 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, 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: May 26, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–13084 Filed 5–29–15; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2007–0265; FRL–9928–64–OAR]

Proposed Information Collection Request; Comment Request; Fine Particulate Matter ($PM_{2.5}$) NAAQS Implementation Rule (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), ''Fine Particulate Matter ($PM_{2.5}$) NAAQS Implementation Rule (Renewal)'' (EPA ICR No. 2258.04, OMB Control No. 2060–0611), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*). Before doing so, the EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed renewal of a currently approved information collection which was originally approved in conjunction with the EPA's now-remanded 2007 final rule addressing implementation-related requirements for the 1997 $PM_{2.5}$ National Ambient Air Quality Standards (NAAQS) and renewed twice since then. On March 23, 2015, the EPA also proposed a new ICR associated with its Notice of Proposed Rulemaking that would replace the remanded 2007 $PM_{2.5}$ NAAQS Implementation Rule. Until that ICR is approved, the existing ICR will remain in effect, subject to approval of this proposed renewal.

DATES: Comments must be submitted on or before July 31, 2015.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OAR–2007–0265, online using *http://www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

The EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information, or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Mr. Cecil (Butch) Stackhouse, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, by phone at (919) 541–5208 or by email at *stackhouse.butch@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *http://www.regulations.gov,* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is (202) 566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, the EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary

for the proper performance of the functions of the agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, the EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Abstract: The final implementation rule for the 1997 $PM_{2.5}$ NAAQS (2007 $PM_{2.5}$ NAAQS Implementation Rule) was promulgated on April 25, 2007 (79 FR 20586). This rule provided the framework of Clean Air Act (CAA) requirements for air agencies to meet in attainment plans to achieve the 1997 $PM_{2.5}$ NAAQS in designated nonattainment areas. States also applied this framework to develop attainment plans for areas designated nonattainment for the 24-hour $PM_{2.5}$ NAAQS revised by the agency in 2006 (74 FR 58688, November 13, 2009; 76 FR 6056; February 3, 2011).

The ICR originally finalized with the 2007 $PM_{2.5}$ NAAQS Implementation Rule had estimated, for the 3 years following the ICR approval date, the burden to air agencies to develop and submit, and the burden to the EPA to review and to approve or disapprove, attainment plans to meet the requirements prescribed in CAA sections 110 and part D, subpart 1 of title I. A $PM_{2.5}$ attainment plan contains rules and other measures designed to improve air quality and achieve the NAAQS by the deadlines established under the CAA. It also must address several additional CAA requirements related to demonstrating timely attainment, and must contain contingency measures in the event the nonattainment area does not achieve reasonable further progress throughout the attainment period or in the event the area does not attain the NAAQS by its attainment date. After a state submits an attainment plan, the CAA requires the EPA to approve or disapprove the plan. Tribes may develop or submit attainment plans, but are not required to do so.

On January 4, 2013, the U.S. Court of Appeals for the District of Columbia Circuit (DC Circuit) remanded the 2007 $PM_{2.5}$ NAAQS Implementation Rule, concluding that the agency had erred in implementing the $PM_{2.5}$ NAAQS according to only the general nonattainment area planning provisions of subpart 1, part D, title I of the CAA, rather than in accordance with the PM-specific planning requirements of subpart 4, part D, title I of the CAA and certain general planning provisions in subpart 1. On March 23, 2015, the EPA proposed a new implementation rule (80 FR 15340) consistent with the attainment planning requirements under CAA subparts 1 and 4 of part D, title I, that would apply to ongoing implementation efforts by air agencies in areas designated nonattainment for the 1997 and 2006 $PM_{2.5}$ NAAQS, as well as to new efforts in areas recently designated nonattainment for the most recent 2012 $PM_{2.5}$ NAAQS. As part of its proposed implementation rule, the EPA also proposed a new ICR to cover the 3-year period after the ICR is approved by OMB, which would account for both the burden associated with plan revisions related to ongoing implementation efforts for the 1997 and 2006 $PM_{2.5}$ NAAQS as well as the additional cost burden to air agencies developing attainment plans for areas designated nonattainment for the 2012 $PM_{2.5}$ NAAQS. Once final, the new ICR will supersede the existing ICR—for which the EPA is proposing renewal in this action—for purposes of $PM_{2.5}$ NAAQS implementation. In the meantime, while the EPA completes its current rulemaking and finalizes the new ICR, the agency is hereby proposing a renewal of the existing ICR that would continue to apply during this interim period.

Respondents/affected entities: State and local governments.

Respondent's obligation to respond: Mandatory.

Currently approved estimated number of respondents: 95 (total).

Frequency of response: Once per triggering event [*i.e.,* each air agency with a newly-designated nonattainment area or an area reclassified to a higher classification is required to revise its State Implementation Plan (SIP)].

Currently approved total estimated burden: 175,400 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $0 annualized capital or operation & maintenance costs.

Changes in estimates: The EPA expects there to be a reduction in excess of 50 percent in the total estimated respondent burden compared with the information collection that is currently approved by OMB. This decrease is due to the fact that the EPA estimates that only six areas may be candidates for reclassification triggering new submittal requirements for the 2006 $PM_{2.5}$ NAAQS, as compared to 31 nonattainment areas initially designated for that NAAQS. In addition, one of the six areas (San Joaquin Valley, CA) remains nonattainment for the 1997 $PM_{2.5}$ NAAQS. The burden estimate, detailed in the supporting statement located in the docket for this proposed renewal, accounts for new SIP revisions from states with nonattainment areas potentially subject to reclassification.

Dated: May 21, 2015.

Stephen D. Page,

Director, Office of Air Quality Planning and Standards, Office of Air and Radiation.

[FR Doc. 2015–13131 Filed 5–29–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9928–46–OGC]

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 (the ''Act''), 42 U.S.C. 7413(g), notice is hereby given of a proposed settlement agreement to address a lawsuit filed by National Parks Conservation Association, Minnesota Center for Environmental Advocacy, Friends of the Boundary Waters, Voyageurs National Park Association, Fresh Energy, and the Sierra Club (collectively, ''Plaintiffs'') and Intervenor Defendant Northern States Power Company Minnesota, d/b/a Xcel Energy in the United States District Court for the District of Minnesota: *National Parks Conservation Association, et al.* v. *EPA,* Civ. No. 12–3043 (D. Minn.). On December 5, 2012, Plaintiffs filed a complaint alleging that the Administrator of the United States Environmental Protection Agency (''EPA'') had failed to perform a

mandatory duty to respond to a 2009 letter by the Department of the Interior (''DOI'') certifying that visibility impairment in Minnesota's Voyageurs National Park and Michigan's Isle Royale National Park is reasonably attributable to emissions from Xcel Energy's coal-fired Sherburne County Generating Station (''Sherco'') in Minnesota. The proposed settlement agreement addresses Plaintiffs' claims and establishes a deadline for EPA to take final action to revise the Minnesota Reasonably Attributable Visibility Impairment (''RAVI'') Federal Implementation Plan (''FIP'').

DATES: Written comments on the proposed settlement agreement must be received by July 1, 2015.

ADDRESSES: Submit your comments, identified by Docket ID number EPA–HQ–OGC–2015–0347, 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: Matthew C. Marks, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone: (202) 564–3276; fax number (202) 564–5603; email address: *marks.matthew@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Additional Information About the Proposed Settlement Agreement

On October 21, 2009, DOI provided a letter to EPA in which DOI stated ''that there exists reasonably attributable impairment of visibility at Voyageurs and Isle Royale due to emissions from the Sherco facility.'' On December 5, 2012, Plaintiffs filed their complaint in this litigation alleging that, since receiving DOI's letter, the Administrator had failed to perform a mandatory duty pursuant to 40 CFR 51.302(c)(4)(iii) and (iv) to promulgate a federal RAVI best available retrofit technology (''BART'') determination for Sherco. In response to the lawsuit, EPA filed an answer on February 1, 2013, denying that the Administrator has a mandatory duty to promulgate RAVI BART for Sherco because EPA has not determined that visibility impairment at one or more Class I areas is reasonably attributable to emissions from Sherco. On March 25, 2015, Plaintiffs filed an Amended Complaint, alleging that the Administrator had failed to perform a mandatory duty ''to identify and analyze for BART each existing stationary facility which may reasonably be anticipated to cause or contribute to impairment of visibility in any mandatory Class I Federal area where the impairment in the mandatory Class I Federal area is reasonably attributable to that existing stationary facility.''

The proposed settlement agreement would resolve the lawsuit filed by Plaintiffs by establishing that EPA will propose to revise the Minnesota RAVI FIP to include specific sulfur dioxide (''SO_2'') emission limitations for Sherco Units 1, 2, and 3, and take final action on the proposal within seven months of the effective date of the settlement agreement. The proposed settlement agreement also provides that nothing in the agreement shall be construed to limit or modify any discretion afforded EPA by the Act or by general principles of administrative law in taking those actions. See the proposed settlement agreement and attachment for specific details.

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 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–2015–0347) 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: May 20, 2015.

Lorie J. Schmidt,

Associate General Counsel.

[FR Doc. 2015–13127 Filed 5–29–15; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to all Interested Parties of the Termination of the Receivership of 10274, NorthWest Bank and Trust, Acworth, Georgia

Notice is hereby given that the Federal Deposit Insurance Corporation (''FDIC'') as Receiver for NorthWest Bank and Trust, Acworth, Georgia (''the Receiver'') intends to terminate its receivership for said institution. The FDIC was appointed receiver of NorthWest Bank and Trust on July 30, 2010. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this Notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this Notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 32.1, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: May 27, 2015.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2015–13121 Filed 5–29–15; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than June 16, 2015.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Ronald J. and Elizabeth A. Schowalter Living Trust, with Ronald J. Schowalter and Elizabeth A. Schowalter as co-trustees, all of Port Washington, Wisconsin; and the Ronald J. and Elizabeth A. Schowalter Living Trust, together as a group acting in concert with Mark D. Schowalter, Port Washington, Wisconsin, individually; the Mark D. Schowalter Family Endowment Trust and Mark D. Schowalter as trustee; the Schowalter Trusts f/b/o Steven R. Schowalter, Mark D. Schowalter, and Sally R. Savatski, with Steven R. Schowalter, Mark D. Schowalter, and Sally A. Savatski as co-trustees; Steven R. Schowalter, Port Washington, Wisconsin, individually; the Steven R. Schowalter Family Endowment Trust and Steven R. Schowalter as trustee; Sally A. Savatski, Port Washington, Wisconsin, individually; the Sally A. Savatski Family Endowment Trust and Sally A. Savatski as trustee; Wendy P. Schowalter, Port Washington, Wisconsin, individually; Catherine J. Schowalter, Port Washington, Wisconsin, individually; Robert A. Savatski, Port Washington, Wisconsin, individually; James S. Schowalter, Port Washington, Wisconsin, individually; Jennifer M. Schowalter, Port Washington, Wisconsin, individually; Mark D. Schowalter, Catherine J. Schowalter, Sally A. Savatski, Robert A. Savatski, James S. Schowalter, and Jennifer M. Schowalter, each as custodians under UGMA for certain Schowalter grandchildren, all of Port Washington, Wisconsin; Tracy N. Schowalter-Braun and Justin P. Braun, individually and as custodians under UGMA for certain Schowalter great-grandchildren, all of Cedarburg, Wisconsin; and the Schowalter Grandchildren's Trust, with Legacy Private Trust Company, as trustee,* all of Neenah, Wisconsin; to retain voting shares of Port Bancshares, Inc., and thereby indirectly retain voting shares of Port Washington State Bank, both in Port Washington, Wisconsin.

Board of Governors of the Federal Reserve System, May 27, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2015–13091 Filed 5–29–15; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Meeting of the Community Preventive Services Task Force (Task Force)

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

ACTION: Notice of meeting.

SUMMARY: The Centers for Disease Control and Prevention (CDC) announces the next meeting of the Community Preventive Services Task Force (Task Force). The Task Force is an independent, nonpartisan, nonfederal, and unpaid panel. Its members represent a broad range of research, practice, and policy expertise in prevention, wellness, health promotion,

and public health, and are appointed by the CDC Director. The Task Force was convened in 1996 by the Department of Health and Human Services (HHS) to identify community preventive programs, services, and policies that increase healthy longevity, save lives and dollars and improve Americans' quality of life. CDC is mandated to provide ongoing administrative, research, and technical support for the operations of the Task Force. During its meetings, the Task Force considers the findings of systematic reviews on existing research, and issues recommendations. Task Force recommendations are not mandates for compliance or spending. Instead, they provide information about evidence-based options that decision makers and stakeholders can consider when determining what best meets the specific needs, preferences, available resources, and constraints of their jurisdictions and constituents. The Task Force's recommendations, along with the systematic reviews of the scientific evidence on which they are based, are compiled in the *Guide to Community Preventive Services (Community Guide).*

DATES: The meeting will be held on Wednesday, June 17, 2015 from 8:30 a.m. to 6:00 p.m. EDT and Thursday, June 18, 2015 from 8:30 a.m. to 1:00 p.m. EDT.

ADDRESSES: The Task Force Meeting will be held at CDC Edward R. Roybal Campus, Tom Harkin Global Communications Center (Building 19), and 1600 Clifton Road NE., Atlanta, GA 30333. You should be aware that the meeting location is in a Federal government building; therefore, Federal security measures are applicable. For additional information, please see Roybal Campus Security Guidelines under **SUPPLEMENTARY INFORMATION**. Information regarding meeting logistics will be available on the Community Guide Web site (*www.thecommunityguide.org*).

Meeting Accessibility: This meeting is open to the public, limited only by space availability. All meeting attendees must RSVP to ensure the required security procedures are completed to gain access to the CDC's Global Communications Center.

U.S. citizens must RSVP by 6/4/2015.

Non U.S. citizens must RSVP by 6/2/2015 due to additional security steps that must be completed. Failure to RSVP by the dates identified could result in the inability to attend the Task Force meeting due to the strict security regulations on federal facilities.

Meeting Accessibility: This meeting is available to the public via Webcast and Conference Call. Individuals may view presentations via Webcast on the Internet. The audio will be presented via conference call. There are only 100 lines available with the Conference Call. The Conference Call numbers and the Webcast URL will be sent to you upon receipt of your RSVP. There are no limitations on the Webcast. All meeting attendees must RSVP to receive the webcast information which will be emailed to you on June 15th.

FOR FURTHER INFORMATION CONTACT: Onslow Smith, The Community Guide Branch; Division of Public Health Information Dissemination; Center for Surveillance, Epidemiology and Laboratory Services; Office of Public Health Scientific Services; Centers for Disease Control and Prevention, 1600 Clifton Road, MS–E–69, Atlanta, GA 30333, phone: (404) 498–6778, email: *CPSTF@cdc.gov* (also contact to RSVP).

SUPPLEMENTARY INFORMATION:

Purpose

The purpose of the meeting is for the Task Force to consider the findings of systematic reviews and issue findings and recommendations. Task Force recommendations provide information about evidence-based options that decision makers and stakeholders can consider when determining what best meets the specific needs, preferences, available resources, and constraints of their jurisdictions and constituents.

Matters To Be Discussed

Task Force Prioritization and Communication of Community Preventive Services Task Force Insufficient Evidence (IE) Findings.

Roybal Campus Security Guidelines

The Edward R. Roybal Campus is the headquarters of the U.S. Centers for Disease Control and Prevention and is located at 1600 Clifton Road NE., Atlanta, Georgia. The meeting is being held in a Federal government building; therefore, Federal security measures are applicable. All meeting attendees must RSVP by the dates outlined under *Meeting Accessibility.*

In planning your arrival time, please take into account the need to park and clear security. All visitors must enter the Edward R. Roybal Campus through the front entrance on Clifton Road. Your car may be searched, and the guard force will then direct visitors to the designated parking area. Upon arrival at the facility, visitors must present government issued photo identification (*e.g.,* a valid federal identification badge, state driver's license, state non-driver's identification card, or passport). Non-United States citizens must complete the required security paperwork prior to the meeting date and must present a valid passport, visa, Permanent Resident Card, or other type of work authorization document upon arrival at the facility. All persons entering the building must pass through a metal detector. Visitors will be issued a visitor's ID badge at the entrance to Building 19 and may be escorted to the meeting room. All items brought to HHS/CDC are subject to inspection.

Dated: May 26, 2015.

Ron A. Otten,

Acting Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2015–13080 Filed 5–27–15; 11:15 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2395–N]

RIN 0938Z

Medicaid Program; State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals (QIs): Federal Fiscal Years 2013 and 2014

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice sets forth the states' final allotments available to pay the Medicare Part B premiums for Qualifying Individuals (QIs) for the federal fiscal year (FY) 2013 and the preliminary QI allotments for FY 2014. The amounts of these QI allotments were determined in accordance with the methodology set forth in regulations and reflect funding for the QI program made available under recent legislation.

DATES: The final QI allotments for payment of Medicare Part B premiums for FY 2013 are effective October 1, 2012. The preliminary QI allotments for FY 2014 are effective October 1, 2013.

FOR FURTHER INFORMATION CONTACT: Diana Kuhn, (410) 786–1914 or Toni Cincibus at (410) 786–2997.

SUPPLEMENTARY INFORMATION:

I. Background

A. QI Allotments for FY 2013

Section 3101 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96, enacted on February 22, 2012) (MCTRJCA) extended the authority and funding for the QI program by providing $280 million,

available for the period October 1, 2012 through December 31, 2012, the first quarter of FY 2013. Section 621 of the American Taxpayer Relief Act of 2012 (Pub. L. 112–240, enacted on January 2, 2013) (ATRA), extended the authority for the QI program for all of FY 2013 and provided $485 million in additional funding for the program for the period January 1, 2013 through September 30, 2013. Therefore the total funding available for the QI program for FY 2013 is $765 million ($280 million plus $485 million).

B. QI Allotments for FY 2014 and Thereafter

As amended by section 621 of the American Taxpayer Relief Act of 2012 (ATRA, Pub. L. 112–240, enacted on January 2, 2013), section 1933(g)(2) of the Social Security Act provided $300 million in funding for the period October 1, 2013 through December 31, 2013, the first quarter of FY 2014. Section 1201 of Division B of the legislation ''Pathway for SGR Reform Act of 2013'' (Pub. L. 113–67 enacted on December 26, 2013) provided an additional $200 million and authority for the QI program for the period January 1, 2014 through March 31, 2014 (second quarter of FY 2014). In addition, section 201 of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93 enacted on April 1, 2014) revised the $200 to $485 million and extended the period for which such funds were available to the end of September 2014. Therefore, a total of $785 million is now available for all of FY 2014 ($300 million for the first quarter of FY 2014, and $485 million for the second through fourth quarters of FY 2014). Finally, section 201 of PAMA further extended the authority and funding for the QI program for FY 2015 as follows: $300 million for the period October 1, 2014 through December 31, 2014 (first quarter of FY 2015); and, $250 million for the period January 1, 2015 through March 31, 2015 (second quarter FY 2015). Therefore, a total of $550 million is available for the QI program for FY 2015.

C. Methodology for Calculating the Fiscal Year QI Allotments

The amounts of the states' final FY 2013 and preliminary FY 2014 QI allotments, contained in this notice, were determined in accordance with the methodology set forth in existing regulations at 42 CFR 433.10(c)(5) and reflect funding for the QI program made available under the legislation discussed above.

II. Tables

The final QI allotments for FY 2013 and the preliminary QI allotments for FY 2014 are shown by state in Table 1 and Table 2, respectively:

Table 1—Final Qualifying Individuals Allotments for October 1, 2012 through September 30, 2013.

Table 2—Preliminary Qualifying Individuals Allotments for October 1, 2013 through September 30, 2014.

TABLE 1—FINAL QUALIFYING INDIVIDUALS ALLOTMENTS FOR OCTOBER 1, 2012 THROUGH SEPTEMBER 30, 2013

State	Initial QI allotments for FY 2013			FY 2013 estimated QI expenditures [1]	Need (difference) If E > D, E − D	Percentage of total need states F/(tot. of F)	Reduction pool for non-need states If D >= E, D − E	Percentage of total non-need states H/(tot. of H)	Reduction adj. for non-need states Col. I × $105,466,335	Increase adj. for need states Col. G × $105,466,335	Final FY 2013 QI allotment [2]
	Number of individuals [3] (000s)	Percentage of total Col B/ Tot. Col B	Initial QI allotment Col C × $765,000,000								
A	B	C	D	E	F	G	H	I	J	K	L
Alabama	38	2.64	$20,159,501	$22,544,081	$2,384,580	2.2610	Need	Need	Need	$2,384,580	$22,544,081
Alaska	2	0.14	1,061,026	326,300	NA	NA	$734,726	0.4320	$455,613	NA	605,414
Arizona	21	1.46	11,140,777	19,563,390	8,422,614	7.9861	Need	Need	Need	8,422,614	19,563,390
Arkansas	27	1.87	14,323,856	13,956,348	NA	NA	367,508	0.2161	227,896	NA	14,095,960
California	107	7.42	56,764,910	28,189,619	NA	NA	28,575,291	16.8015	17,719,883	NA	39,045,026
Colorado	16	1.11	8,488,211	6,005,621	NA	NA	2,482,589	1.4597	1,539,484	NA	6,948,727
Connecticut	15	1.04	7,957,698	3,902,339	NA	NA	4,055,359	2.3844	2,514,777	NA	5,442,921
Delaware	4	0.28	2,122,053	3,211,361	1,089,308	1.0328	Need	Need	Need	1,089,308	3,211,361
District of Columbia	2	0.14	1,061,026	0	NA	NA	1,061,026	0.6239	657,955	NA	403,071
Florida	96	6.66	50,929,265	72,316,568	21,387,303	20.2788	Need	Need	Need	21,387,303	72,316,568
Georgia	45	3.12	23,873,093	34,507,397	10,634,304	10.0831	Need	Need	Need	10,634,304	34,507,397
Hawaii	6	0.42	3,183,079	1,409,689	NA	NA	1,773,390	1.0427	1,099,701	NA	2,083,378
Idaho	7	0.49	3,713,592	2,677,626	NA	NA	1,035,967	0.6091	642,415	NA	3,071,177
Illinois	68	4.72	36,074,896	24,744,637	NA	NA	11,330,259	6.6619	7,026,031	NA	29,048,864
Indiana	43	2.98	22,812,067	5,829,210	NA	NA	16,982,857	9.9854	10,531,275	NA	12,280,791
Iowa	16	1.11	8,488,211	4,584,319	NA	NA	3,903,892	2.2954	2,420,851	NA	6,067,360
Kansas	18	1.25	9,549,237	5,023,657	NA	NA	4,525,580	2.6609	2,806,367	NA	6,742,870
Kentucky	34	2.36	18,037,448	15,065,051	NA	NA	2,972,397	1.7477	1,843,219	NA	16,194,229
Louisiana	29	2.01	15,384,882	20,831,932	5,447,049	5.1647	Need	Need	Need	5,447,049	20,831,932
Maine	7	0.49	3,713,592	6,075,634	2,362,042	2.2396	Need	Need	Need	2,362,042	6,075,634
Maryland	24	1.66	12,732,316	8,959,072	NA	NA	3,773,244	2.2186	2,339,834	NA	10,392,482
Massachusetts	28	1.94	14,854,369	9,694,545	NA	NA	5,159,824	3.0338	3,199,669	NA	11,654,700
Michigan	38	2.64	20,159,501	14,816,534	NA	NA	5,342,966	3.1415	3,313,238	NA	16,846,263
Minnesota	22	1.53	11,671,290	6,389,653	NA	NA	5,281,637	3.1055	3,275,207	NA	8,396,083
Mississippi	18	1.25	9,549,237	15,212,658	5,663,421	5.3699	Need	Need	Need	5,663,421	15,212,658
Missouri	39	2.70	20,690,014	4,395,160	NA	NA	16,294,854	9.5809	10,104,636	NA	10,585,377
Montana	6	0.42	3,183,079	1,543,785	NA	NA	1,639,294	0.9639	1,016,546	NA	2,166,533
Nebraska	6	0.42	3,183,079	2,283,431	NA	NA	899,648	0.5290	557,882	NA	2,625,197
Nevada	10	0.69	5,305,132	5,391,707	86,575	0.0821	Need	Need	Need	86,575	5,391,707
New Hampshire	6	0.42	3,183,079	2,269,086	NA	NA	913,993	0.5374	566,778	NA	2,616,301
New Jersey	40	2.77	21,220,527	7,810,549	NA	NA	13,409,979	7.8847	8,315,690	NA	12,904,836
New Mexico	9	0.62	4,774,619	4,117,952	NA	NA	656,667	0.3861	407,207	NA	4,367,412
New York	85	5.89	45,093,620	46,198,147	1,104,527	1.0473	Need	Need	Need	1,104,527	46,198,147
North Carolina	38	2.64	20,159,501	29,670,994	9,511,493	9.0185	Need	Need	Need	9,511,493	29,670,994
North Dakota	3	0.21	1,591,540	670,202	NA	NA	921,338	0.5417	571,333	NA	1,020,207
Ohio	54	3.74	28,647,712	26,381,913	NA	NA	2,265,799	1.3322	1,405,049	NA	27,242,662
Oklahoma	27	1.87	14,323,856	10,320,039	NA	NA	4,003,816	2.3541	2,482,815	NA	11,841,041
Oregon	17	1.18	9,018,724	14,297,554	5,278,830	5.0052	Need	Need	Need	5,278,830	14,297,554
Pennsylvania	78	5.41	41,380,028	33,265,180	NA	NA	8,114,848	4.7713	5,032,115	NA	36,347,913
Rhode Island	6	0.42	3,183,079	2,439,790	NA	NA	743,289	0.4370	460,923	NA	2,722,156
South Carolina	33	2.29	17,506,935	14,903,998	NA	NA	2,602,937	1.5305	1,614,113	NA	15,892,822
South Dakota	4	0.28	2,122,053	1,623,719	NA	NA	498,334	0.2930	309,023	NA	1,813,030
Tennessee	48	3.33	25,464,632	31,271,663	5,807,030	5.5061	Need	Need	Need	5,807,030	31,271,663
Texas	106	7.35	56,234,397	78,081,412	21,847,015	20.7147	Need	Need	Need	21,847,015	78,081,412
Utah	6	0.42	3,183,079	2,018,266	NA	NA	1,164,813	0.6849	722,315	NA	2,460,765
Vermont	2	0.14	1,061,026	3,574,197	2,513,171	2.3829	Need	Need	Need	2,513,171	3,574,197
Virginia	23	1.60	12,201,803	14,128,876	1,927,073	1.8272	Need	Need	Need	1,927,073	14,128,876
Washington	23	1.60	12,201,803	5,963,337	NA	NA	6,238,466	3.6680	3,868,548	NA	8,333,255

West Virginia	17	1.18	9,018,724	6,218,910	NA	NA	2,799,814	1.6462	1,736,199	NA	7,282,525
Wisconsin	22	1.53	11,671,290	4,839,536	NA	NA	6,831,754	4.0169	4,236,453	NA	7,434,837
Wyoming	3	0.21	1,591,540	873,450	NA	NA	718,090	0.4222	445,296	NA	1,146,244
Total	1,442	100.00	765,000,000	700,390,091	105,466,335	100.0000	170,076,244	100.0000	105,466,335	105,466,335	765,000,000

Footnotes:
[1] FY 2013 Estimates from July 2013 CMS Survey of States; Estimates Are For Months October 2012 Through September 2013.
[2] For Need States, Final FY 2013 QI Allotment is equal to Initial QI Allotment in Column D increased by amount in Column K; For Non-Need States, Final FY 2013 QI Allotment is equal to Initial QI Allotment in Column D reduced by amount in Column J.
[3] Three-year average (2009–2011) of number (000) of Medicare beneficiaries in State who are not enrolled in Medicaid but whose incomes are at least 120% but less than 135% of Federal poverty level.
Source: Census Bureau Annual Social and Economic Supplement (ASEC) to the 2012 Current Population Survey (CPS).

TABLE 2—PRELIMINARY QUALIFYING INDIVIDUALS ALLOTMENTS FOR OCTOBER 1, 2013 THROUGH SEPTEMBER 30, 2014

State	Initial QI allotments for FY 2014			FY 2014 estimated QI expenditures [1]	Need (difference) if E > D, E − D	Percentage of total need states F/(tot. of F)	Reduction pool for non-need states if D >= E, D − E	Percent of total non-need states H/(tot. of H)	Reduction adj. for non-need states Col. I × $116,087,180	Increase adj. for need states Col. G × $116,087,180	Preliminary FY 2014 QI allotment [2]
	Number of individuals [3] (000s)	Percentage of total Col B/tot. Col B	Initial QI allotment Col C × $785,000,000								
A	B	C	D	E	F	G	H	I	J	K	L
Alabama	33	2.13	$16,756,145	$24,304,910	$7,548,766	6.5027	Need	Need	Need	$7,548,766	$24,304,910
Alaska	2	0.13	1,015,524	374,073	NA	NA	$641,451	0.4288	$497,751	NA	517,772
Arizona	29	1.88	14,725,097	21,719,024	6,993,927	6.0247	Need	Need	Need	6,993,927	21,719,024
Arkansas	25	1.62	12,694,049	14,283,289	1,589,240	1.3690	Need	Need	Need	1,589,240	14,283,289
California	130	8.41	66,009,056	29,497,236	NA	NA	36,511,819	24.4061	28,332,367	NA	37,676,689
Colorado	12	0.78	6,093,144	6,744,021	650,877	0.5607	Need	Need	Need	650,877	6,744,021
Connecticut	15	0.97	7,616,429	5,030,002	NA	NA	2,586,428	1.7289	2,007,011	NA	5,609,418
Delaware	5	0.32	2,538,810	3,208,262	669,452	0.5767	Need	Need	Need	669,452	3,208,262
District of Columbia	2	0.13	1,015,524	0	NA	NA	1,015,524	0.6788	788,024	NA	227,500
Florida	133	8.60	67,532,342	78,905,990	11,373,648	9.7975	Need	Need	Need	11,373,648	78,905,990
Georgia	46	2.98	23,357,050	37,475,498	14,118,447	12.1619	Need	Need	Need	14,118,447	37,475,499
Hawaii	6	0.39	3,046,572	1,472,570	NA	NA	1,574,002	1.0521	1,221,391	NA	1,825,181
Idaho	8	0.52	4,062,096	2,684,609	NA	NA	1,377,487	0.9208	1,068,899	NA	2,993,196
Illinois	63	4.08	31,989,004	28,168,168	NA	NA	3,820,836	2.5540	2,964,885	NA	29,024,119
Indiana	41	2.65	20,818,241	6,077,393	NA	NA	14,740,848	9.8534	11,438,573	NA	9,379,668
Iowa	17	1.10	8,631,953	4,924,019	NA	NA	3,707,935	2.4785	2,877,276	NA	5,754,678
Kansas	18	1.16	9,139,715	5,698,955	NA	NA	3,440,760	2.3000	2,669,954	NA	6,469,761
Kentucky	35	2.26	17,771,669	17,488,089	NA	NA	283,580	0.1896	220,052	NA	17,551,617
Louisiana	29	1.88	14,725,097	22,748,614	8,023,517	6.9116	Need	Need	Need	8,023,517	22,748,614
Maine	7	0.45	3,554,334	7,632,104	4,077,771	3.5127	Need	Need	Need	4,077,771	7,632,104
Maryland	22	1.42	11,170,763	10,821,904	NA	NA	348,860	0.2332	270,707	NA	10,900,056
Massachusetts	27	1.75	13,709,573	10,070,400	NA	NA	3,639,173	2.4326	2,823,918	NA	10,885,655
Michigan	37	2.39	18,787,193	18,446,036	NA	NA	341,157	0.2280	264,730	NA	18,522,462
Minnesota	18	1.16	9,139,715	6,901,960	NA	NA	2,237,755	1.4958	1,736,449	NA	7,403,266
Mississippi	20	1.29	10,155,239	16,214,118	6,058,879	5.2192	Need	Need	Need	6,058,879	16,214,118
Missouri	44	2.85	22,341,527	6,154,273	NA	NA	16,187,253	10.8203	12,560,952	NA	9,780,575
Montana	6	0.39	3,046,572	1,617,663	NA	NA	1,428,909	0.9551	1,108,802	NA	1,937,770
Nebraska	7	0.45	3,554,334	2,347,662	NA	NA	1,206,672	0.8066	936,351	NA	2,617,983
Nevada	7	0.45	3,554,334	6,220,570	2,666,236	2.2968	Need	Need	Need	2,666,236	6,220,570
New Hampshire	6	0.39	3,046,572	2,755,828	NA	NA	290,744	0.1943	225,611	NA	2,820,961
New Jersey	45	2.91	22,849,288	8,686,979	NA	NA	14,162,310	9.4667	10,989,640	NA	11,859,648
New Mexico	9	0.58	4,569,858	4,491,904	NA	NA	77,953	0.0521	60,490	NA	4,509,368
New York	102	6.60	51,791,721	47,248,495	NA	NA	4,543,226	3.0369	3,525,443	NA	48,266,278
North Carolina	48	3.10	24,372,574	31,199,358	6,826,784	5.8807	Need	Need	Need	6,826,784	31,199,358
North Dakota	4	0.26	2,031,048	708,704	NA	NA	1,322,343	0.8839	1,026,109	NA	1,004,938

TABLE 2—PRELIMINARY QUALIFYING INDIVIDUALS ALLOTMENTS FOR OCTOBER 1, 2013 THROUGH SEPTEMBER 30, 2014—Continued

State	Initial QI allotments for FY 2014			FY 2014 estimated QI expenditures [1]	Need (difference) if E > D, E − D	Percentage of total need states F/(tot. of F)	Reduction pool for non-need states if D >= E, D − E	Percent of total non-need states H/(tot. of H)	Reduction adj. for non-need states Col. I × $116,087,180	Increase adj. for need states Col. G × $116,087,180	Preliminary FY 2014 QI allotment [2]
	Number of individuals [3] (000s)	Percentage of total Col B/tot. Col B	Initial QI allotment Col C × $785,000,000								
A	B	C	D	E	F	G	H	I	J	K	L
Ohio	59	3.82	29,957,956	27,260,048	NA	NA	2,697,908	1.8034	2,093,517	NA	27,864,439
Oklahoma	23	1.49	11,678,525	11,187,585	NA	NA	490,940	0.3282	380,959	NA	11,297,566
Oregon	16	1.03	8,124,191	16,228,030	8,103,839	6.9808	Need	Need	Need	8,103,839	16,228,030
Pennsylvania	83	5.37	42,144,243	33,836,544	NA	NA	8,307,699	5.5532	6,446,591	NA	35,697,652
Rhode Island	5	0.32	2,538,810	2,519,698	NA	NA	19,112	0.0128	14,830	NA	2,523,979
South Carolina	33	2.13	16,756,145	15,105,600	NA	NA	1,650,545	1.1033	1,280,786	NA	15,475,358
South Dakota	3	0.19	1,523,286	2,110,798	587,512	0.5061	Need	Need	Need	587,512	2,110,798
Tennessee	43	2.78	21,833,765	32,496,447	10,662,682	9.1851	Need	Need	Need	10,662,682	32,496,447
Texas	108	6.99	54,838,292	78,683,812	23,845,519	20.5410	Need	Need	Need	23,845,519	78,683,813
Utah	7	0.45	3,554,334	2,394,138	NA	NA	1,160,196	0.7755	900,286	NA	2,654,047
Vermont	3	0.19	1,523,286	3,813,371	2,290,085	1.9727	Need	Need	Need	2,290,085	3,813,371
Virginia	33	2.13	16,756,145	14,627,256	NA	NA	2,128,889	1.4230	1,651,971	NA	15,104,174
Washington	26	1.68	13,201,811	6,660,311	NA	NA	6,541,500	4.3726	5,076,060	NA	8,125,751
West Virginia	20	1.29	10,155,239	6,415,789	NA	NA	3,739,450	2.4996	2,901,731	NA	7,253,508
Wisconsin	22	1.42	11,170,763	4,908,586	NA	NA	6,262,178	4.1859	4,859,312	NA	6,311,452
Wyoming	4	0.26	2,031,048	915,357	NA	NA	1,115,690	0.7458	865,751	NA	1,165,297
Total	1,546	100.00	785,000,000	751,486,048	116,087,180	100.0000	149,601,132	100.0000	116,087,180	116,087,180	785,000,000

Footnotes:

[1] FY 2014 Estimates in Column E are from July 2013 CMS Survey of States; Estimates are for months October 2013 through September 2014.

[2] For Need States, Preliminary FY 2014 QI Allotment is equal to Initial QI Allotment in Column D increased by amount in Column K; For Non-Need States, Preliminary FY 2014 QI Allotment is equal to Initial QI Allotment in Column D reduced by amount in Column J.

[3] Three-year average (2010–2012) of number (000) of Medicare beneficiaries in State who are not enrolled in Medicaid but whose incomes are at least 120% but less than 135% of Federal poverty level.

Source: Census Bureau Annual Social and Economic Supplement (ASEC) to the 2012 Current Population Survey (CPS).

The following describes the information contained in the columns of Table 1 and Table 2:

Column A—*State.* Column A shows the name of each state. Columns B through D show the determination of an Initial QI Allotment for FY 2013 (Table 1) or FY 2014 (Table 2) for each state, based only on the indicated Census Bureau data.

Column B—*Number of Individuals.* Column B contains the estimated average number of Medicare beneficiaries for each state that are not covered by Medicaid whose family income is at least 120 but less than 135 percent of the federal poverty level. With respect to the *final FY 2013 QI allotment (Table1),* Column B contains the number of such individuals for the years 2009 through 2011, as obtained from the Census Bureau's Annual Social and Economic Supplement to the 2012 Current Population Survey. With respect to the *preliminary FY 2014 QI allotment (Table 2),* Column B contains the number of such individuals for the years 2010 through 2012, as obtained from the Census Bureau's Annual Social and Economic Supplement to the Current Population Survey.

Column C—*Percentage of Total.* Column C provides the percentage of the total number of individuals for each state, that is, the Number of Individuals for the state in Column B divided by the sum total of the Number of Individuals for all States in Column B.

Column D—*Initial QI Allotment.* Column D contains each state's Initial QI Allotment for FY 2013 (Table 1) or FY 2014 (Chart 2), calculated as the state's Percentage of Total in Column C multiplied by the total amount available nationally for QI allotments for the fiscal year. The total amount available nationally for QI allotments each fiscal year is $765,000,000 for FY 2013 (Table 1) and $785,000,000 for FY 2014 (Table 2).

Columns E through L show the determination of the States' Final QI Allotments for FY 2013 (Table 1) or Preliminary QI Allotments for FY 2014 (Table 2).

Column E—*FY 2013 or FY 2014 Estimated QI Expenditures.* Column E contains the states' estimates of their total QI expenditures for FY 2013 (Table 1) or FY 2014 (Table 2) based on information obtained from states in the summer of 2013 and as updated.

Column F—*Need (Difference).* Column F contains the additional amount of QI allotment needed for those states whose estimated expenditures in Column E exceeded their Initial QI allotments in Column D for FY 2013 (Table 1) or for FY 2014 (Table 2) for such states, Column F shows the amount in Column E minus the amount in Column D. For other ''Non-Need'' states, Column F shows ''NA.''

Column G—*Percent of Total Need States.* For states whose projected QI expenditures in Column E are greater than their Initial QI allotment in Column D for FY 2013 (Table 1) or FY 2014 (Table 2), respectively, Column G shows the percentage of total need, determined as the amount for each Need State in Column F divided by the sum of the amounts for all states in Column F. For Non-Need states, the entry in Column G is ''NA.''

Column H—*Reduction Pool for Non-Need States.* Column H shows the amount of the pool of surplus QI allotments for FY 2013 (Table 1) or FY 2014 (Table 2), respectively, for those states that project QI expenditures for the fiscal year that are less than the Initial QI allotment for the fiscal year (referred to as Non-Need states). For states for which the estimates in Column E of QI expenditures for FY 2013 or FY 2014, respectively, are equal to or less than their Initial QI allotments in Column D for FY 2013 or FY 2014, respectively, Column H shows the amount in Column D minus the amount in Column E. For the states with a need, Column H shows ''Need.'' The reduction pool of excess QI allotments is equal to the sum of the amounts in Column H.

Column I—*Percent of Total Non-Need States.* For states whose projected QI expenditures in Column E are less than their Initial QI allotment in Column D for FY 2013 (Table 1) or FY 2014 (Table 2), Column I shows the percentage of the total reduction pool in Column H, determined as the amount for each Non-Need state in Column H divided by the sum of the amounts for all states in Column H. For Need states, the entry in Column I is ''Need''.

Column J—*Reduction Adjustment for Non-Need States.* Column J shows the amount of adjustment needed to reduce the Initial QI allotments in Column D for FY 2013 (Table 1) or FY 2014 (Table 2) for Non-Need States in order to address the total need shown in Column F. The amount in Column J is determined as the percentage in column I for Non-Need States multiplied by the lesser of the total need in Column F (equal to the sum of Needs in Column F) or the total Reduction Pool in Column H (equal to the sum of the Non-Need amounts in Column H). For Need States, the entry in Column J is ''Need.''

Column K—*Increase Adjustment for Need States.* Column K shows the amount of adjustment to increase the Initial QI Allotment in Column D for FY 2013 (Table 1) or FY 2014 (Table 2) for Need States in order to address the total need shown for the fiscal year in Column F. The amount in Column K is determined as the percentage in Column G for Need States multiplied by the lesser of the total need in Column F (equal to the sum of Needs in Column F) or the total Reduction Pool in Column H (equal to the sum of the Non-Need amounts in Column H). For Non-Need States, the entry in Column K is ''NA.''

Column L—*Final FY 2013 QI Allotment (Chart 1) or Preliminary FY 2014 QI Allotment (*Table *2).* Column L contains the Final QI Allotment for each state for FY 2013 (Table 1) or the Preliminary QI Allotment for FY 2014 (Table 2). For states that need additional QI allotment amounts for the fiscal year based on Estimated QI Expenditures in Column E as compared to their Initial QI allotments in Column D for the fiscal year (states with a projected need amount are shown in Column F), Column L is equal to the Initial QI allotment in Column D for FY 2013 (Table 1) or FY 2014 (Table 2) plus the amount determined in Column K for Need States. For Non-Need States (states with a projected surplus in Column H), Column L is equal to the QI Allotment in Column D reduced by the Reduction Adjustment amount in Column J.

III. Collection of Information Requirements

This notice does not impose any information collection or recordkeeping requirements. Consequently, it does not need Office of Management and Budget review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: April 17, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: May 21, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015–13043 Filed 5–28–15; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–5513–N]

Medicare Program; Announcement of Request for Applications for the Million Hearts® Cardiovascular Risk Reduction Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS

ACTION: Notice.

SUMMARY: This notice informs interested parties of an opportunity to apply for participation in the Million Hearts® Cardiovascular Risk Reduction Model. The primary goal of this model is to test whether encouraging physician practices to calculate risk for all of the practice's eligible Medicare beneficiaries, using the American College of Cardiology/American Heart Association (ACC/AHA) Atherosclerotic Cardiovascular Disease (ASCVD) 10-year pooled cohort risk calculator will prevent the occurrence of first-time heart attacks and strokes.

DATES: Applications will be considered timely if they are received on or before September 4, 2015 as outlined in the Request for Applications (RFA).

Note: Interested applicants will be required to submit a non-binding Letter of Intent (LOI) to apply for the model.

ADDRESSES: All LOIs must be submitted electronically through the Center for Medicare and Medicaid Innovation Web site at: *http://innovation.cms.gov/initiatives/Million-Hearts-CVDRRM/.* LOIs will be accepted throughout the entire application period, ending September 4, 2015. Applicants will need to use their LOI confirmation number to access the RFA. All applicants will receive a RFA submission confirmation number; it is the applicant's responsibility to retain a copy of the confirmation number for proof of submission.

FOR FURTHER INFORMATION CONTACT: Nina Brown at (410) 786–6103 or email address: *mhmodel@cms.hhs.gov.* The Center for Medicare and Medicaid Innovation Web site is at *http://innovation.cms.gov/.*

SUPPLEMENTARY INFORMATION:

I. Background

The Center for Medicare and Medicaid Innovation (Innovation Center), within the Centers for Medicare & Medicaid Services (CMS), was created to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care for Medicare, Medicaid, and Children's Health Insurance Program beneficiaries.

We are interested in models designed to improve care for specific populations. One population is Medicare fee-for service (FFS) beneficiaries 18 to 79 years of age who have never had a heart attack or stroke and who are not under hospice care. Current evidence suggests that preventive cardiovascular disease interventions can significantly reduce both adverse cardiovascular-related outcomes and death. The Million Hearts® Cardiovascular Risk Reduction Model (hereinafter referred to as ''CVD Risk Reduction Model'') seeks to test whether providing incentives for physician practices to calculate absolute 10-year cardiovascular risk reduction, measured by the American College of Cardiology/American Heart Association (ACC/AHA) 10-year pooled cohort risk calculator, is effective in reducing heart attacks and strokes among Medicare FFS beneficiaries. Intervention group practices will engage in shared decision making, team-based care, and population health management to reduce beneficiaries' absolute risk. Intervention group practices will be required to submit quality data to CMS supported by a per-beneficiary-per-month payment.

The Innovation Center is operating this model under the authority of section 1115A of the Social Security Act (the act) (42 U.S.C. 1315a) (as added by section 3021 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 known as Affordable Care Act)). We will evaluate whether this model reduces the occurrence of heart attacks and strokes as well as Medicare expenditures and enhances the quality of care furnished to Medicare beneficiaries.

II. Provisions of the Notice

The RFA is directed to physician practices that include private practices, hospital-owned physician practices, large medical networks, hospital/physician organization, or independent practice associations. Up to 720 practices are expected to participate. Participating practices must meet the following requirements:

- Practices must have at least one practitioner. Practitioners are defined as Medical Doctors, Doctors of Osteopathic Medicine, Physician Assistants, and Nurse Practitioners.
- Practices must be using an Office of the National Coordinator for Health Information Technology (ONC) certified electronic health record (EHR) system.
- Participating physicians or other eligible professionals within the practice must have met the criteria for the Medicare EHR Incentive Programs in performance year 2015, also known as ''meaningful use,'' of an ONC certified electronic health record.

Practices selected to participate will be randomized to the intervention group or the control group. Practices randomized to the control group will be required to submit data to CMS at the beginning of the first, second, third and fifth years of the model. Control group practices will receive a one-time payment of $20 per-beneficiary following the successful transmission of data to CMS on eligible beneficiaries within their practices. Practices randomized to the control group will receive no further funding beyond this one-time payment.

Practices randomized to the intervention group will be paid a one-time upfront payment of $10 per-beneficiary to conduct initial risk stratification for eligible beneficiaries in addition to a $10 per-beneficiary-per-month fee for ongoing monitoring of high-risk FFS Medicare beneficiaries. Starting in the second year of the model, the $10 per-beneficiary-per-month ongoing fee is gradually placed at risk based on a practice's performance managing its ''high-risk'' beneficiaries.

Intervention group practices in the CVD Risk Reduction Model will use the ACC/AHA Atherosclerotic Cardiovascular Disease (ASCVD) 10-year pooled cohort risk calculator to risk stratify Medicare FFS beneficiaries 18 to 79 years of age meeting the inclusion criteria. Practices will further identify whether beneficiaries are ''high-risk'' defined by their 10-year ASCVD risk score: A ''high risk,'' beneficiary is defined as a beneficiary with an ACC/AHA 10-year ASCVD risk score greater than or equal to 30 percent. Once the high risk beneficiaries have been identified, intervention group practices will engage in risk modification and report process and outcome measures of their results. Practices will be required to submit annual data to CMS through a certified Data Registry, which will be provided to participating practices by CMS.

The CVD Risk Reduction Model period of performance is 5 years. Selected practices will enter into Model Participant Agreements with CMS. Applicants must present evidence that the applicant practices are capable of successfully identifying beneficiaries who meet the CVD Risk Reduction Model eligibility requirements.

Applicants must also demonstrate their plans for engaging in shared decision making activities with their beneficiaries. Applicants are required to submit to CMS general beneficiary data, the clinical indicators needed to calculate the 10-year ASCVD risk score, and the cardiovascular Physician Quality Reporting System (PQRS) measures as outlined in the RFA. Eligible practices will be selected on a first come, first served basis until all 720 spots have been filled. Applications must be submitted timely in the standard format outlined in the CVD Risk Reduction Model RFA in order to be considered for review. Applications that are not received in this format will not be considered for review.

For more specific details regarding the CVD Risk Reduction Model (including the RFA), we refer applicants to the informational materials on the Innovation Center Web site at: *http://innovation.cms.gov/initiatives/Million-Hearts-CVDRRM/.* Applicants are responsible for monitoring the Web site to obtain the most current information available.

III. Collection of Information Requirements

Section 1115A(d)(3) of the Social Security Act states that chapter 35 of title 44, United States Code (the Paperwork Reduction Act of 1995), shall not apply to the testing and evaluation of models or expansion of the models under this section. Consequently, there is no need for this document to be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Dated: May 15, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–13042 Filed 5–28–15; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1804]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Studies To Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach To Establish an Acute Reference Dose; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #232 entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose (ARfD)'' (VICH GL54). This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft VICH guidance document is intended to address the nature and types of data that can be useful in determining an ARfD for residues of veterinary drugs, the studies that may generate such data, and how the ARfD may be calculated based on these data.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 31, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Policy and Regulations Staff (HFV–6), 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 request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Tong Zhou, Center for Veterinary Medicine (HFV–153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0826, *Tong.Zhou@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #232 entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose (ARfD)'' (VICH GL54). 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 Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) 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; FDA; 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.

Six 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, one representative from the industry of Canada, one representative from the government of South Africa, and one representative from the industry of South Africa. 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. Draft Guidance on Studies To Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach To Establish an Acute Reference Dose (ARfD)

The VICH Steering Committee held a meeting in February 2015 and agreed that the draft guidance document entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose (ARfD)'' (VICH GL54) should be made available for public comment. This draft VICH guidance document is intended to address the nature and types of data that can be useful in determining an ARfD for residues of veterinary drugs, the studies that may generate such data, and how the ARfD may be calculated based on these data.

FDA and the VICH Expert Working Group will consider comments about the draft guidance document.

III. Significance of Guidance

This draft guidance, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose (ARfD). It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

This draft 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 Action of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

VI. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: May 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13105 Filed 5–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1960]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; MedWatch: The Food and Drug Administration Medical Products Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 1, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0291. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

MedWatch: The FDA Medical Products Reporting Program OMB Control Number 0910–0291—Extension

I. Background

To ensure the marketing of safe and effective products, it is critical that postmarketing adverse outcomes and product problems are reported for all FDA-regulated human healthcare products, including drugs (prescription and nonprescription), biologics, medical devices, dietary supplements and other special nutritional products (*e.g.* infant formula and medical foods), and cosmetics. To facilitate reporting on human medical products (except vaccines) during their postapproval and marketed lifetimes, three forms (collectively known as the MedWatch forms) are available from the Agency. Form FDA 3500 is intended to be used for voluntary (*i.e.,* not mandated by law or regulation) reporting by healthcare professionals. Form FDA 3500B is written in plain language and is intended to be used for voluntary reporting (*i.e.,* not mandated by law or regulation) by consumers (*i.e.,* patients and their caregivers). Form FDA 3500A is used for mandatory reporting (*i.e.,* required by law or regulation). When FDA receives this information from healthcare professionals, patients, or consumers, the report becomes data that will be used to assess and evaluate the risk associated with the product. FDA will then take whatever action is necessary to reduce, mitigate, or eliminate the public's exposure to the risk through regulatory and public health interventions.

Authorizing Statutes and Codified Regulations

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353b, 355, 360i, 360*l,* and 393) and the Public Health Service Act (42 U.S.C. 262) represent the statutory authority for the FDA to collect mandatory adverse event reports from regulated industry on medical products once approved for marketing to monitor the safety of drugs, biologics, medical devices, and dietary

supplements. There are no laws or regulations mandating the postmarket reporting for medical foods, infant formula, cosmetics, or tobacco products, and the reporting for these products is done voluntarily.

Requirements regarding mandatory reporting of adverse events or product problems have been codified in parts 310, 314, 600, and 803 (21 CFR 310, 314, 600, and 803), specifically §§ 310.305, 314.80, 314.98, 600.80, 803.30, 803.50, 803.53, 803.56, and specified in sections 503B, 760, and 761 (21 U.S.C. 379aa and 379aa–1) of the FD&C Act. Mandatory reporting of adverse reactions for human cells, tissues, and cellular- and tissue-based products (HCT/Ps) has been codified in 21 CFR 1271.350.

II. Use of Form 3500 (Voluntary Reporting)

This voluntary version of the form may be used by healthcare professionals to submit all reports not mandated by Federal law or regulation. Individual health professionals are not required by law or regulation to submit reports to the Agency or the manufacturer with the exception of certain adverse reactions following immunization with vaccines as mandated by the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 300aa–1). Reports for vaccines are not submitted via MedWatch or MedWatch forms, but are submitted to the Vaccines Adverse Event Reporting System (see *http://vaers.hhs.gov*), which is jointly administered by FDA and the Centers for Disease Control and Prevention.

Hospitals are not required by Federal law or regulation to submit reports associated with drug products, biological products, or special nutritional products. However, hospitals and other user facilities are required by Federal law to report medical device-related deaths and serious injuries.

Under Federal law and regulation, section 761(b)(1) of the FD&C Act, a dietary supplement manufacturer, packer, or distributor whose name appears on the label of a dietary supplement marketed in the United States is required to submit to FDA any serious adverse event report it receives regarding use of the dietary supplement in the United States. However, FDA bears the burden to gather and review evidence that a dietary supplement may be adulterated under section 402 of the FD&C Act (21 U.S.C. 342) after that product is marketed. Therefore, the Agency depends on the voluntary reporting by health professionals, and especially by consumers, of suspected serious adverse events and product quality problems associated with the use of dietary supplements. All dietary supplement reports were previously received by the Agency on paper versions of Form FDA 3500 (or Form FDA 3500B) (by mail or fax). Currently, electronic reports may be sent to the Agency via an online submission route called the Safety Reporting Portal (*http://www.safetyreporting.hhs.gov/*). In that case, Form FDA 3500 (or Form FDA 3500B) is not used.

Form FDA 3500 may be used to report to the Agency serious adverse events, product problems, and product use errors and therapeutic failures. The form is provided in both paper and electronic formats. Reporters may mail or fax paper forms to the Agency (a fillable PDF version of the form is available at *http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf*) or reporters may electronically submit a report via the MedWatch Online Voluntary Reporting Form (*https://www.accessdata.fda.gov/scripts/medwatch/*). Reporting is supported for drugs, non-vaccine biologicals, medical devices, special nutritional products, cosmetics, and non-prescription (over the counter (OTC)) human drug products marketed without an approved application. The paper form may also be used to submit reports about tobacco products and dietary supplements. Electronic reports for tobacco products and dietary supplements may be submitted to the Agency via an online submission route called the Safety Reporting Portal (*http://www.safetyreporting.hhs.gov/*).

III. Use of Form 3500B (Consumer Voluntary Reporting)

This voluntary version of the form may be used by consumers (*i.e.* patients and their caregivers) to submit reports not mandated by Federal law or regulation. Individual patients or their caregivers are not required by law or regulation to submit reports to the Agency or the manufacturer.

FDA supports and encourages direct reporting to the Agency by consumers of suspected serious adverse outcomes and other product problems associated with human medical products, (*http://www.fda.gov/Safety/ReportaProblem/default.htm*). Since the inception of the MedWatch program, launched in July 1993 by then FDA Commissioner David Kessler, the program has been promoting and facilitating voluntary reporting by both the general public and healthcare professionals. FDA has further encouraged voluntary reporting by requiring inclusion of the MedWatch toll-free phone number or the MedWatch Internet address on all outpatient drug prescriptions dispensed, as mandated by section 17 of the Best Pharmaceuticals for Children Act (Pub. L. 107–109).

On March 25, 2008, section 906 of the Food and Drug Administration Amendments Act (Pub. L. 110–85) amended section 502(n) of the FD&C Act and mandated that published direct-to-consumer advertisements for prescription drugs include the following statement printed in conspicuous text (this includes vaccine products): ''You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *www.fda.gov/safety/medwatch,* or call 1–800–FDA–1088.''

Most private vendors of consumer medication information, the drug product-specific instructions dispensed to consumers at outpatient pharmacies, remind patients to report ''side effects'' to FDA and provide contact information to permit reporting via the MedWatch process.

Since 2013, FDA has made available Form FDA 3500B. It was proposed during the previous authorization in 2012 and is a version of Form FDA 3500 that is tailored for consumers and written in plain language (in conformance with the Plain Writing Act of 2010 (Pub. L. 111–274) *http://www.gpo.gov/fdsys/pkg/PLAW-111publ274/pdf/PLAW-111publ274.pdf*).

Form FDA 3500B evolved from several iterations of draft versions, with input from human factors experts, from other regulatory agencies, and with extensive input from consumer advocacy groups and the general public. Form FDA 3500B may be used to report to the Agency adverse events, product problems, and product use errors. The form is provided in both paper and electronic formats. Reporters may mail or fax paper forms to the Agency (a fillable PDF version of the form is available at *http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf*) or electronically submit a report via the MedWatch Online Voluntary Reporting Form (*https://www.accessdata.fda.gov/scripts/medwatch/*). Reporting is supported for drugs, non-vaccine biologicals, medical devices, special nutritional products, cosmetics, and non-prescription OTC human drug products marketed without an approved application. The paper form may also be used to submit reports about tobacco products and dietary supplements.

Electronic reports for tobacco products and dietary supplements may be submitted to the Agency via an online submission route called the

Safety Reporting Portal (*http://www.safetyreporting.hhs.gov/*).

IV. Use of Form FDA 3500A (Mandatory Version)

A. Drug and Biological Products

In sections 505(b), 505(j) (21 U.S.C. 354(b) and (j)), 503B, and 704 (21 U.S.C. 374) of the FD&C Act, Congress has required that important safety information relating to all human drug products be made available to the FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the FD&C Act (21 U.S.C. 372) authorizes investigational powers to the FDA for enforcement of the FD&C Act. These statutory requirements regarding mandatory reporting have been codified by FDA under parts 310 and 314 (drugs) and 600 (biological products). Mandatory reporting of adverse reactions for HCT/Ps has been codified in § 1271.350.

B. OTC Monograph Drug Products and Dietary Supplements

Section 760 of the FD&C Act provides for mandatory safety reporting for non-prescription human drug products marketed without an approved application as described in the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Pub. L. 109–462), which became law on December 22, 2006. The law requires manufacturers, packers, and distributors of nonprescription, OTC human drug products marketed without an approved application (OTC monograph drug products) to submit reports of adverse experiences from domestic sources. The law also requires reports of serious adverse events to be submitted to FDA by manufacturers of dietary supplements.

C. Postmarketing Safety Reports—Changes in Format Starting in June 2015

Current requirements specify that postmarketing adverse experience reports must be submitted on paper on Form FDA 3500A (or the Council for International Organizations of Medical Sciences) I form for serious, unexpected adverse experiences from a foreign source). For the last several years the Agency has accepted electronic submissions in lieu of the paper Form FDA 3500A on the condition they are submitted in a manner that the Agency can process, review, and archive. On June 10, 2014, the Agency issued a final rule entitled ''Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements'' (79 FR 33072) that requires electronic submission of all mandatory postmarketing safety reports, including individual case safety reports. Entities with mandatory reporting obligations under parts 310 and 314 (drugs) and 600 (biological products) and specified under section 760 of the FD&C Act must implement this rule within 1 year of the issuance date (by June 10, 2015). For more information, go to *http://www.gpo.gov/fdsys/pkg/FR-2014-06-10/pdf/2014-13480.pdf*.

D. Medical Device Products

Section 519 of the FD&C Act (21 U.S.C. 360i) requires manufacturers and importers of devices intended for human use to establish and maintain records, make reports, and provide information, as the Secretary of Health and Human Services may, by regulation, reasonably be required to provide assurance that such devices are not adulterated or misbranded and to otherwise assure its safety and effectiveness. The Safe Medical Devices Act of 1990 (Pub. L. 101–629), signed into law on November 28, 1990, amends section 519 of the FD&C Act. The amendment requires that user facilities such as hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities report deaths related to medical devices to FDA and to the manufacturer, if known. Serious illnesses and injuries are to be reported to the manufacturer or to FDA if the manufacturer is not known. These statutory requirements regarding mandatory reporting have been codified by FDA under part 803. Part 803 mandates the use of Form FDA 3500A for reporting to FDA on medical devices. The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250), signed into law October 26, 2002, amended section 519 of the FD&C Act. The MDUFMA amendment (section 303) required FDA to revise the MedWatch forms to facilitate the reporting of information relating to reprocessed single-use devices, including the name of the re-processor and whether the device has been reused.

V. Proposed Modifications to Existing Forms FDA 3500, 3500A, and 3500B

A. General Changes

The proposed modifications to Forms FDA 3500 and 3500A reflect changes that will bring the forms into conformation, since the previous authorization in 2012, with current regulations, rules, and guidances.

B. Changes Proposed for Form FDA 3500

Formatting modifications are proposed to several fields to enhance the clarity and utility of the information collected. In section A2, it is proposed that checkboxes for years, months, weeks, and days be added to permit clarity about the age of the patient. In section A4, it is proposed that checkboxes for pounds (lb) and kilograms (kg) be added to permit clarity about the patient's weight. To permit clarity and utility for the dates being reported, it is proposed that field labels and instructions be modified to ask the reporter to use the format DD–MMM–YYYY. A watermark will be added to the date fields to prompt the reporter to enter data using this format. This proposed change will reduce the data-entry burden for FDA by making the form more easily scanned by the optical character recognition (OCR) software used by the Agency. This change is proposed for all of the date fields on the form including: A2 (Date of Birth), B2 (Death), B3, B4, C (Returned to Manufacturer On), D7, E4 (Expiration Date), E6, and E7.

In recognition of OMB 1997 Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity, and as part of FDA's Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data (*http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/UCM410474.pdf*) developed in response to the requirement in section 907 of the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 (Pub. L.112–144), changes are proposed to the location and formatting of the fields containing data about the patient's race. It is proposed that race be deleted from the descriptor in section B, field B7, that requests ''Other Relevant History, Including Preexisting Medical Conditions (*e.g.* allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.).'' Instead, it is proposed that a new race and ethnicity field be added to section A, ''Patient Information.'' The proposed ethnicity field will be numbered 5a and state ''Ethnicity (Check single best answer)'' with corresponding checkboxes for ''Hispanic/Latino'' and ''Not Hispanic/Latino.'' Adjacent to this field, the ''Race'' field will be numbered 5b and state ''Race (Check all that apply).'' It will contain checkboxes for ''Asian,'' ''American Indian or Alaskan Native,'' ''Black or African American,''

''White,'' and ''Native Hawaiian or Other Pacific Islander.''

Changes are proposed to the location, formatting, and labeling of fields related to the suspect product and its availability for evaluation to allow the product's identifying information to be grouped in one place, and increase the likelihood that this information is entered. In section D, field D1 will be used to request data for ''Name and Strength,'' ''Manufacturer/Compounder,'' as well as ''Lot #,'' and ''NDC # or Unique ID #'' for up to two suspect medical products.

In 2013, the Drug Quality and Security Act (Pub. L. 113–54) added new section 503B to the FD&C Act, under which a compounder may elect to become an outsourcing facility by registering with FDA. Outsourcing facilities are required to report adverse events to FDA in accordance with the content and format requirements established through guidance or regulation under § 310.305. In addition to mandatory reporting, many adverse events related to compounded drugs are reported voluntarily by healthcare professionals and consumers. Therefore, FDA is proposing changes to the voluntary versions of the MedWatch forms (*i.e.* Forms FDA 3500 and 3500B) to improve the ability to rapidly identify reports involving compounded drugs. The existing field (section D, field D1) that contains the descriptor ''Manufacturer'' will be relabeled ''Manufacturer/Compounder.'' Correspondingly, a checkbox for ''Manufacturer/Compounder'' will be added to the existing field (section G, field G4) ''Also Reported to.'' It is proposed that a new field be added to the section entitled ''Suspect Products.'' The new field will be numbered and include a descriptor ''Is the Product Compounded?'' with corresponding checkboxes for ''Yes'' or ''No.''

The new field will also include a descriptor ''Is the Product Over-the-Counter'' with corresponding checkboxes for ''Yes'' or ''No.'' The instructions to the form will be updated accordingly. The form remains a three-page form with all the main data fields on page one, with instructions for use and a self-addressed, postage-paid return mailer on the reverse side of page one, and page three being a continuation page for additional information should reporters need extra space.

C. Changes Proposed for Form FDA 3500A

Formatting modifications are proposed to several fields to enhance the clarity and utility of the information collected. In section A2, it is proposed that checkboxes for years, months, weeks, and days be added to permit clarity about the age of the patient. In section A4, it is proposed that checkboxes for pounds (lb) and kilograms (kg) be added to permit clarity about the patient's weight. To permit clarity and utility for the dates being reported, it is proposed that field labels and instructions be modified to ask the reporter to use the format DD–MMM–YYYY. A watermark will be added to the date fields to prompt the reporter to enter data using this format. This proposed change will reduce the data-entry burden for FDA by making the form more easily scanned by the OCR software used by the Agency. This change is proposed for all of the date fields on the form including: A2 (Date of Birth), B2 (Death), B3, B4, C7, D4 (Expiration Date), D6, D7, D10 (Returned to Manufacturer on), F6, F8, F11, F13, G4, and H4.

In recognition of OMB's 1997 Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity, and as part of FDA's Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data (*http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/UCM410474.pdf*) developed in response to the requirement in section 907 of FDASIA, changes are proposed to the location and formatting of the fields containing data about the patient's race. It is proposed that race be deleted from the descriptor in section B, field B7, that requests ''Other Relevant History, Including Preexisting Medical Conditions (*e.g.* allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.).'' Instead, it is proposed that a new race and ethnicity field be added to section A, ''Patient Information.'' The proposed ethnicity field will be numbered 5a, and state ''Ethnicity (Check single best answer)'' with corresponding checkboxes for ''Hispanic/Latino'' and ''Not Hispanic/Latino.'' Adjacent to this field, the ''Race'' field will be numbered 5b, and state ''Race (Check all that apply).'' It will contain checkboxes for ''Asian,'' ''American Indian or Alaskan Native,'' ''Black or African American,'' ''White,'' and ''Native Hawaiian or Other Pacific Islander.''

Changes are proposed to the location, formatting, and labeling of fields related to the suspect product and its availability for evaluation to allow the product's identifying information to be grouped in one place and increase the likelihood that this information is entered. For consistency and clarity, it is proposed that many of the fields in the suspect products sections on Forms FDA 3500 and 3500A be mirrored. For Form FDA 3500A, it is proposed that the current section C, field C1, ''Name (Give labeled strength & mfr/labeler),'' also be used to request data for ''Lot #'' and ''NDC # or Unique ID #.'' Section C, field C1 will be relabeled ''Name, Manufacturer/Compounder, Strength.'' Proposed field C1 will contain distinct areas for ''Name and Strength,'' ''Manufacturer/Compounder,'' ''NDC # or Unique ID #,'' and ''Lot #'' for up to two suspect products. Since the information will now be captured in proposed field C1, separate fields for ''Lot #'' and ''NDC #/Unique ID #'' (C6 and C9 from the current form) will not be needed. The currently numbered field C2, ''Dose, Frequency & Route Used,'' will be renumbered C3. It will also be reformatted to have three distinct areas for dose, frequency, and route, respectively, for up to two suspect products. Current field C3, ''Therapy Dates,'' will be renumbered C4, and current field C4, ''Diagnosis for Use,'' will be renumbered C5. Current field C5, ''Event Abated After Use Stopped or Dose Reduced,'' will be renumbered C9, and field C8, ''Event Reappeared After Reintroduction?'' will be renumbered C10. The field for expiration date will be renumbered C8, and the field for concomitant medical products and therapy dates (current field C10) will be renumbered C2.

As stated previously, in 2013, the Drug Quality and Security Act added new section 503B to the FD&C Act, under which a compounder may elect to become an outsourcing facility by registering with FDA. Outsourcing facilities are required to report adverse events to FDA in accordance with the content and format requirements established through guidance or regulation under § 310.305. To facilitate implementation of this mandatory reporting requirement, changes will need to be made to the existing Form FDA 3500A. It is proposed that a new field be added to section G1 that contains the descriptor ''Compounding Outsourcing Facility 503B?'' with a corresponding checkbox for ''Yes.'' It is also proposed that a new field be added to section C, ''Suspect Products.'' The new field will be numbered C6 and include a descriptor ''Is the Product Compounded?'' with corresponding checkboxes for ''Yes'' or ''No'' (for up to two suspect products). The instructions to the form will be updated accordingly.

In addition, a new field numbered C7 will be added and ''Is the Product Over-the-Counter?'' with corresponding

checkboxes for ''Yes'' or ''No'' (for up to two suspect products). The instructions to the form will be updated accordingly.

Additionally, for clarity, in section G, field G5, the area labeled ''(A)NDA #'' will be split into two separate areas—one for ''ANDA #'' and one for ''NDA #.''

D. Changes Proposed for Form FDA 3500B

For consistency, and to improve the quality of the data received, the changes being proposed on the voluntary Form FDA 3500 (for use by healthcare professionals) are also being proposed on the voluntary Form FDA 3500B (for use by consumers). Formatting modifications are being proposed to several fields to enhance the quality, utility, and clarity of the information. In section D, the field entitled ''Age (at time the problem occurred) or Birth Date'' will be separated into separate fields for age and date of birth. In the field for ''Age,'' checkboxes for years, months, weeks, and days will be added to permit clarity about the age of the patient. Similarly, for the field in section D labeled ''Weight,'' checkboxes for pounds (lb) and kilograms (kg) will be added to permit clarity about the patient's weight. The instructions will be modified accordingly. To permit clarity about the dates being reported, field labels and instructions will be modified to ask the reporter to use the format DD–MMM–YYYY. A watermark will be added to the field to prompt the reporter to respond using this format. This will also reduce the data entry burden by making the form more easily scanned by the OCR software used by FDA. All of the date fields on the form will be affected by this proposed change. These include section A (date the problem occurred, death), section B (expiration date, date the person first started taking or using this product, date the person stopped taking or using this product), section C (date the implant was put in, date the implant was taken out), section D (date of birth), and section E (today's date).

A formatting modification to the field in section D that is currently labeled ''Race'' is being proposed in recognition of OMB 1997 Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity, and as part of FDA's Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data (*http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/UCM410474.pdf*) developed in response to the requirement in section 907 of FDASIA. It is proposed that the field be relabeled ''Race (Check all that apply)'' and contain checkboxes for ''Asian,'' ''American Indian or Alaskan Native,'' ''Black or African American,'' ''White,'' and ''Native Hawaiian or Other Pacific Islander.'' It is also proposed that the field contain an adjacent area labeled ''Ethnicity (Check single best answer)'' with corresponding checkboxes for ''Hispanic/Latino'' and ''Not Hispanic/Latino.''

As discussed previously in this notice, many adverse events related to compounded drugs are reported voluntarily by healthcare professionals and consumers. Therefore, FDA is proposing changes to the voluntary versions of Forms FDA 3500 and 3500B to improve the Agency's ability to rapidly identify reports involving compounded drugs. FDA proposes to add a field to section B with the label ''Is the Product Compounded?'' and corresponding checkboxes for ''Yes'' or ''No.'' FDA also proposes to add a field to section B with the label ''Is the Product Over-the-Counter'' with corresponding checkboxes for ''Yes'' or ''No.''

Finally, to improve clarity and to be consistent with Form FDA 3500, FDA proposes to reword the last field of section E that currently asks ''May we give your name and contact information to the company that makes the product (manufacturer) to help them evaluate the product?'' to ''If you do NOT want your identity disclosed to the manufacturer, place an 'X' in this box.''

Items that we proposed in the 60-day notice that have changed: The proposed change to Form FDA 3500 to merge sections C and D has been retracted; therefore, the sections will not be re-sequenced on Form FDA 3500. For the proposed new field ''Is product compounded or over-the-counter'' (proposed on Forms FDA 3500, 3500A and 3500B), the descriptor ''Check all that apply'' will be deleted and these will be broken out into two separate questions, in two separate fields, with corresponding ''Yes'' and ''No'' checkboxes for up to two suspect products. The proposal to add a new ''compounder'' checkbox to Form 3500 Field G4 has been retracted. Instead the existing manufacturer checkbox will be relabeled ''manufacturer/compounder.'' The proposal to add a new field ''Product Available for Evaluation?'' to the ''suspect products'' section of the Form FDA 3500A was retracted. The proposed changes outlined above reflect these differences. We have reviewed the name address field for Forms FDA 3500 and 3500A and believe data quality would be improved if separate fields for last name, first name, address, state, ZIP code, and Country were also included instead of one field labeled ''name and address'' to capture all of that information.

In the **Federal Register** of December 11, 2014 (79 FR 73591), FDA published a 60-day notice requesting public comment on the proposed collection of information. Four comments were received.

Comments Affecting All Three FDA Forms (3500, 3500A, 3500B)

(Comment 1) One commenter recommended the option of an ''unknown'' check box for race/ethnicity.

(Response) FDA disagrees with this comment as it is inconsistent with the OMB standards for the classification of Federal data on race and ethnicity.

(Comment 2) One commenter requested an implementation date of 18 months after publication of the finalized form.

(Response) FDA will allow sufficient time for implementation.

Comments Affecting FDA Forms 3500 and 3500A

(Comment 1) Section G Field 4 and Section C Field 6: We propose to add a third checkbox labeled ''unknown'' for when this type of information is not received. Rationale: This information may not be received.

(Response) FDA disagrees. G4 corresponds to ''Date Received by Manufacturer'' on Form FDA 3500A. This is a required element and the manufacturer should always have this information. C6 corresponds to Lot # on the existing Form FDA 3500A. If this information is unknown the field should be left blank.

(Comment 2) In Section A1: Along with Patient Identifier, in bracket (first, last) can be added for better identification.

(Response) FDA disagrees. Capturing this data may discourage people from submitting voluntary reports. The instructions for the form state ''Do not use the patient's name or social security number.''

(Comment 3) In Section A2, Age group can be added.

(Response) FDA disagrees. The WG believes that the two data elements proposed for age—Age with checkboxes for days, weeks, months, years, and date of birth in the format DD–MMM–YYYY are sufficient to capture this data.

(Comment 4) In Section A3, after selecting Female, a check box should populate for pregnancy with options Yes, No, UNK. Pregnancy can be removed from section B7.

(Response) FDA disagrees. The Agency believes pregnancy status is captured sufficiently well through existing field B7.

(Comment 5) In Section B1, if Product problem check box is selected then only a text box to enter NDC# should come as National Drug Code is required ONLY when reporting a drug product problem. It can be removed from C9.

(Response) FDA disagrees. Product problem is not limited to drug products, and may include medical devices, biologics, and other products which would not have an associated NDC number.

(Comment 6) In section B2, Hospitalization—initial or prolonged can be relabeled to only Hospitalization and can have three check boxes; Initial, Prolonged and Hospital discharge summary available. Reporter can select whichever is applicable.

(Response) FDA Disagrees. We encourage reporters to put more detail about the hospitalization in the narrative text.

(Comment 7) In section B5, Describe Event or Problem, along with individual event terms, seriousness criteria for each event should be populated, so that event-wise seriousness criteria can be identified.

(Response) FDA disagrees. An event is considered serious if it meets the regulatory definition, as outlined in §§ 310.305, 314.80, 600.80, 803.3, and 1271.

Comments Affecting Form FDA 3500

None.

Comments Affecting Form FDA 3500A

(Comment 1) Action taken with drug can be added in section C.

(Response) FDA disagrees. This information equates to product use stopped or dose reduced, which is already captured on Forms FDA 3500 and 3500A.

(Comment 2) We propose that the FDA require medical device adverse reporting use the MedDRA dictionary instead of the Patient Problem Codes. Rationale: Currently when reporting adverse events for medical devices, the current dictionary used is the ''Patient Problem Codes of the Center for Devices and Radiological Health.'' This dictionary is much smaller (~800 terms) than the widely used MedDRA dictionary used when reporting adverse events with drugs (~20.6K terms). Using the MedDRA dictionary in place of the Patient Problem Codes would allow for more accurate recording of patient adverse events.

(Response) FDA disagrees. FDA will continue to use Patient Problem Codes for medical devices instead of MedDRA coding. While the MedDRA dictionary is able to adequately capture adverse events with drugs, patient problem codes and device problem codes are more effective at capturing device related adverse events.

(Comment 3) Causality scale can be added in Section C.

(Response) FDA Disagrees. Causality is not assessed at the reporting level. Refer to §§ 310.305(g), 314.80(k), 600.80(k)(1), and 803.16.

(Comment 4) In section C10, Concomitant Medical Products and Therapy Dates (Exclude treatment of event), Dose of concomitant drugs should also be included.

(Response) FDA disagrees. Concomitant medical products are not limited to drug products, and may include medical devices, biologics, and other regulated products. As concomitant products are not suspected to be related to the adverse event, it is not necessary to capture the dose.

(Comment 5) In Section E1, along with Phone#, Email address can also be included.

(Response) FDA disagrees. Form FDA 3500A, section E already includes a field for email address, as does Forms FDA 3500, section G, and 3500B. However, we have reviewed the name address field for Forms FDA 3500 and 3500A and believe data quality would be improved if separate fields for last name, first name, address, state, ZIP code, and Country were also included instead of one field labeled ''name and address'' to capture all of that information.

Comments Affecting Form 3500B

(Comment 1) One commenter urged the inclusion of a Spanish version of Form FDA 3500B.

(Response) FDA agrees with the importance of communicating the benefits and risks of medical products to healthcare providers and patients, especially underrepresented populations, including those with limited English proficiency. FDA's language access plan (*http://www.fda.gov/ForConsumers/ByAudience/MinorityHealth/ucm412582.htm*) outlines some of the steps FDA is taking to improve communications with underrepresented populations. FDA's drug safety communications are currently translated into Spanish and are available at *http://www.fda.gov/Drugs/DrugSafety/ucm263010.htm*. FDA is also working to improve the quality of the data received in adverse event reports received directly from consumers. At this time, FDA plans to focus resources on improving data quality from English-language consumer reports before evaluating how to best handle product experience information from non-English speaking consumers.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

FDA center/21 CFR section/FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total
Center for Biologics Evaluation and Research/Center for Drug Evaluation and Research:					
Form FDA 3500	14,727	1	14,727	0.66 (40 minutes)	9,720
Form FDA 3500A (§§ 310.305, 314.80, 314.98, 600.80, 1271.350).	599	98	58,702	1.21	71,029
Form FDA 3500A (§ 310.305 outsourcing facilities).	50	2	100	1.21	121
Center for Devices and Radiological Health:					
Form FDA 3500	5,233	1	5,233	0.66 (40 minutes)	3,454
Form 3500A (§ 803)	2,277	296	673,992	1.21	815,530
Center for Food Safety and Applied Nutrition:					
Form FDA 3500	1,793	1	1,793	0.66 (40 minutes)	1,183
Form 3500A	1,659	1	1,659	1.21	2,007
Center for Tobacco Products Form FDA 3500	39	1	39	0.66 (40 minutes)	26

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—Continued

FDA center/21 CFR section/FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total
All Centers Form FDA 3500B	13,750	1	13,750	0.46 (30 minutes)	6,325
Total					909,395

Dated: May 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13102 Filed 5–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1798]

Patient-Focused Drug Development for Alpha-1 Antitrypsin Deficiency; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for Alpha-1 Antitrypsin Deficiency (AATD). Patient-Focused Drug Development is an FDA performance commitment under the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to provide FDA with patients' perspectives on the impact on daily life of AATD. FDA also is seeking patients' perspectives on the available therapies for this disorder.

DATES: The public meeting will be held on September 29, 2015, from 9 a.m. to 3:30 p.m. Registration to attend the meeting must be received by September 15, 2015. Registration from those individuals interested in presenting comments as part of the panel discussions should be received by July 31, 2015. See the **SUPPLEMENTARY INFORMATION** section for instructions on how to register for the meeting. Submit either electronic or written comments by November 30, 2015.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993. Entrance for public meeting participants (non-FDA employees) is through Building 1, where routine security checks will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Submit electronic comments 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. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Barbara Kass, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 1125, Silver Spring, MD 20993, 240–402–6887, FAX: 301–595–1243, email: *PatientFocused_CBER@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected AATD as the focus of a public meeting under the Patient-Focused Drug Development initiative. This initiative involves obtaining a better understanding of patients' perspectives on the challenges posed by AATD and the impact of current therapies for this condition. The Patient-Focused Drug Development initiative is being conducted to fulfill FDA performance commitments that are part of the PDUFA reauthorization under Title I of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144). The full set of performance commitments is available on the FDA Web site at *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.*

FDA has committed to obtaining the patient perspective on 20 disease areas during the course of PDUFA V. For each disease area, the Agency will conduct a public meeting to discuss the disease and its impact on patients' daily lives, the types of treatment benefits that matter most to patients, and patients' perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient communities, and other interested stakeholders.

On April 11, 2013, FDA published a notice in the **Federal Register** (78 FR 21613) that announced the disease areas for meetings in fiscal years (FY) 2013–2015, the first 3 years of the 5-year PDUFA V timeframe. The Agency used several criteria outlined in the April 11, 2013, notice to develop the list of disease areas. FDA obtained public comment on the Agency's proposed criteria and potential disease areas through a public docket and a public meeting that was convened on October 25, 2012. In selecting the set of disease areas, FDA carefully considered the public comments received and the perspectives of review divisions at FDA. FDA has initiated a second public process for determining the disease areas for meetings in FY 2016–2017 and published a notice in the **Federal Register** on October 8, 2014 (79 FR 60857). More information, including the list of disease areas and a general schedule of meetings, is posted on FDA's Web site at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm.*

II. Purpose and Scope of the Meeting

The purpose of this Patient-Focused Drug Development meeting is to obtain input on the symptoms and other impacts that matter most to patients with AATD. FDA also intends to seek patients' perspectives on current approaches to treating this disorder. FDA expects that this information will come directly from patients, caregivers, and patient advocates.

Individuals with AATD have low serum levels of Alpha-1-Antitrypsin (AAT, also known as Alpha-1 proteinase inhibitor (A1–PI)) and increased risks of developing a form of chronic obstructive lung disease called emphysema and, less frequently, liver disease. Some AATD patients with emphysema have symptoms of asthma. There are different genetic forms of the disease, but even among people with the same genetic form and similar levels of AAT in their blood, there is tremendous diversity in

clinical severity. A substantial percentage of individuals with severe AATD never develop symptomatic lung disease during their lifetimes. Others may develop the first signs and symptoms of lung disease between the ages of approximately 25 and 50 years, or older. Affected individuals often develop emphysema, which is a lung disease caused by damage to the small air sacs in the lung. Progression of emphysema in AATD may lead to respiratory failure, a need for lung transplantation, and eventually death. The only specific medication approved for raising the blood levels of AAT in severe AATD patients with emphysema is weekly intravenous treatment with A1–PI (Human) purified from human blood plasma.

Severe AATD patients may also develop liver disease as infants, during childhood, or as adults. There is wide variation in the severity of liver disease among affected patients. Currently, no specific therapy for AATD-related liver disease is available other than liver transplantation, so the focus in these patients is on the prevention and management of other types of liver damage.

The questions that will be asked of patients and patient caregivers at the meeting are provided in this document. The meeting will be divided into two main topics: (1) The effects of Alpha-1 Antitrypsin Deficiency that matter most to you, and (2) perspectives on current approaches to treatment. For each topic, a brief patient panel discussion will begin the dialogue. This will be followed by a facilitated discussion inviting comments from other patient and patient caregiver participants. In addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions through electronic or written comments, which can be submitted to the Division of Dockets Management (see **ADDRESSES**). For context, please indicate if you are commenting as a patient with AATD or on behalf of a child or loved one.

Topic 1: The effects of Alpha-1 Antitrypsin Deficiency that matter most to you.

- Of all of the symptoms that you experience because of your condition, which one to three symptoms have the most significant impact on your life? (Examples may include:

(a) For lung disease: shortness of breath during specific activities or at rest, chronic cough, wheezing, weight loss, exacerbations of particular symptoms;

(b) For liver disease: abdominal pain, loss of appetite, height and weight concerns.)

- Are there specific activities that are important to you, but that you cannot do at all, or as well as you would like, because of your condition? Please describe, using specific examples. (Examples may include: Participating in physical activities, attending work/school and family/social activities.)
- How have your condition and its symptoms changed over time?
- What worries you most about your condition?

Topic 2: Perspectives on current approaches to treatment.

- What are you currently doing to treat your condition or its symptoms? (Examples may include:

(a) For lung disease: Inhaled bronchodilators, inhaled corticosteroids, intravenous augmentation therapy with A1–PI (Human) on a regular or intermittent basis;

(b) For liver disease: Ursodiol.)

- How well do these treatments work for you?
- What are the most significant disadvantages or complications of your current treatments, and how do they affect your daily life?
- How has your treatment changed over time and why?
- What aspects of your condition are not improved by your current treatment regimen?
- What treatment has had the most positive impact on your life?
- If you could create your ideal treatment, what would it do for you (*i.e.,* what specific things would you look for in an ideal treatment)?
- If you had the opportunity to consider participating in a clinical trial studying experimental treatments, what things would you consider when deciding whether or not to participate?

III. Attendance and Registration

If you wish to attend this meeting, visit *https://www.eventbrite.com/e/public-meeting-on-patient-focused-drug-development-for-alpha-1-antitrypsin-deficiency-tickets-15617092143.* If you do not have access to the Internet, you may mail or fax your registration information (including name, title, affiliation, address, email address, telephone, and fax numbers) to Barbara Kass (see **FOR FURTHER INFORMATION CONTACT**) by September 15, 2015. There is no registration fee for the public meeting. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Registration on the day of the public meeting will be provided on a space available basis beginning at 8 a.m. Those who are unable to attend the meeting in person can register to view a live Web cast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Web cast.

If you need special accommodations because of disability, please contact Barbara Kass at least 7 days in advance. FDA will post the agenda approximately 5 days before the meeting at *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/MeetingsMeetingsConferences/ucm435242.htm.*

IV. Comments

Patients and patient caregivers who are interested in presenting comments as part of the panel discussions should register by July 31, 2015. You will be asked to indicate in your registration which topic(s) you wish to address and to send a brief summary of responses to the topic questions to *PatientFocused_CBER@fda.hhs.gov* by July 31, 2015. Panelists will be notified of their selection soon after August 28, 2015. FDA will try to accommodate all patients and patient caregivers who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

Regardless of attendance at the public meeting, interested persons may submit either electronic or written responses to any or all of the questions pertaining to topics 1 and 2 to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. To ensure consideration, submit comments by November 30, 2015. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

V. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm435242.htm* and at *http://www.regulations.gov.* It may also be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent

to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: May 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13063 Filed 5–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–N–0161]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Current Good Manufacturing Practices for Blood and Related Regulations for and Blood Components; and Requirements for Donor Testing, Donor Notification, and ''Lookback''

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Current Good Manufacturing Practices for Blood and Related Regulations for and Blood Components; and Requirements for Donor Testing, Donor Notification, and 'Lookback' '' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On March 11, 2015, the Agency submitted a proposed collection of information entitled, ''Current Good Manufacturing Practices for Blood and Related Regulations for and Blood Components; and Requirements for Donor Testing, Donor Notification, and 'Lookback' '' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0116. The approval expires on May 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: May 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13064 Filed 5–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1659]

Established Conditions: Reportable Chemistry, Manufacturing, and Controls Changes for Approved Drug and Biologic Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Established Conditions: Reportable CMC Changes for Approved Drug and Biologic Products.'' The purpose of this guidance is to provide applicants of new drug applications, abbreviated new drug applications, and biologic license applications with FDA's current thinking on established conditions (*i.e.,* the chemistry, manufacturing, and controls (CMC) information in a submission that would require reporting to FDA if changed for approved drug and biologic products, per the current regulations). This guidance also describes those sections of a common technical document formatted application that typically contain information that meets the definition of established conditions, and provides considerations for managing changes to established conditions over the life cycle of an approved product.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 31, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ashley Boam, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–2400; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Established Conditions: Reportable CMC Changes for Approved Drug and Biologic Products.'' The current regulations for drugs and biologics require applicants with approved drug or biologic products to notify FDA about each change in each condition established in the approved application beyond the variations already provided for in the application (see 21 CFR 314.70) or each change in the product, production process, quality controls, equipment, facilities, responsible personnel, or labeling established in the approved license application (see 21 CFR 601.12). FDA guidance documents clarify the recommended reporting mechanism (*i.e.,* supplement, annual report) for postapproval CMC changes. This draft guidance has been developed to address the lack of clarity with respect to what CMC information in an application constitutes an established condition.

A better understanding of which elements of the CMC information constitute established conditions to FDA and where in an application these are generally expected to be described will allow for a more effective postapproval submission strategy (*e.g.,* effective use of risk management

principles in the International Conference on Harmonisation (ICH) Q9, and knowledge management as defined in ICH Q10) by the regulated industry. This will also provide the FDA pathways to better regulate postapproval changes by utilizing more flexibility and risk-based principles, as envisioned by the pharmaceutical product quality initiatives laid out in FDA's ''Pharmaceutical Current Good Manufacturing Practices (cGMPs) for the 21st Century—A Risk Based Approach'' (see *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/QuestionsandAnswersonCurrentGoodManufacturingPracticescGMPforDrugs/UCM071836*).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Established Conditions: Reportable CMC Changes for Approved Drug and Biologic Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Paperwork Reduction Act

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 211, 314, and 601 have been approved under OMB control numbers 0910–0139, 0910–0001, and 0910–0338, respectively.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: May 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13104 Filed 5–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than July 31, 2015.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 594–4306.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Rural Outreach Benefits Counseling Program Measures OMB No. 0915–XXXX—New.

Abstract: The Rural Outreach Benefits Counseling Program (Benefits Counseling Program) is authorized by section 330A(e) of the Public Health Service (PHS) Act (42 U.S.C. 254c(e)), as amended, to ''promote rural health care services outreach by expanding the delivery of health care services to include new and enhanced services in rural areas.'' The purpose of the 3-year Benefits Counseling Program is to expand outreach, education, and enrollment efforts to eligible uninsured and newly insured individuals and families in rural communities.

The overarching goals of this grant funding are to coordinate and conduct innovative outreach activities through a strong consortium in order to: (1) Identify and enroll uninsured individuals and families who are eligible for public health insurance, such as Medicare, Medicaid, and the Children's Health Insurance Program, and qualified health plans offered through Health Insurance Marketplaces and/or private health insurance plans in rural communities and (2) educate the newly insured individuals and families in rural communities about their health insurance benefits, help connect them to primary care and preventive services to which they now have access, and help them retain their health insurance coverage.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993. These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy (FORHP), including: (a) Access to care; (b) population demographics; (c) staffing; (d) consortium/network; (e) sustainability; and (f) benefits counseling process and outcomes. Several measures will be used for the Benefits Counseling Program. All measures will speak to FORHP's progress toward meeting the goals set.

Likely Respondents: The respondents will be recipients of the Rural Outreach Benefits Counseling Program grant funding.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. 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. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized burden hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average urden per response in hours)	Total burden hours
Rural Outreach Benefits Counseling Grant Program Measures	10	1	10	1.5	15
Total	10	1	10	1.5	15

HRSA specifically requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–13088 Filed 5–29–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Ryan Asherin, Oregon Health Authority: Based on the report of an investigation conducted by the Oregon Health Authority (OHA) and analysis conducted by ORI in its oversight review, ORI found that Ryan Asherin, former Surveillance Officer and Principal Investigator, OHA, Public Health Division engaged in research misconduct in research supported by the Centers for Disease Control and Prevention (CDC) Emerging Infections Program Grant 5U01CI00306–05.

ORI found that the Respondent engaged in research misconduct by falsifying and/or fabricating data that were included in the CDC research record, a manuscript submitted to *JAMA Intern Med* in January 2013, a published CDC report (*CDC Morbidity and Mortality Weekly Report* 61(09):157–162, March 2012), and presentations in 2012 to CDC and at the 11th Biennial Congress of the Anaerobe Society.

ORI found that the Respondent falsified and/or fabricated fifty-six (56) case report forms (CRFs) while acquiring data on the incidence of *Clostridium difficile* infections in Klamath County, Oregon. Specifically, the Respondent (1) fabricated responses to multiple questions on the CRFs for patient demographic data, patient health information, and *Clostridium difficile* infection data, including the diagnoses of toxic megacolon and ileus and the performance of a colectomy, with no evidence in patient medical records to support the responses; and (2) falsified the CRFs by omitting data on the CRFs that clearly were included in patient medical records.

Mr. Asherin has entered into a Voluntary Settlement Agreement (Agreement) and has voluntarily agreed for a period of two (2) years, beginning on May 12, 2015:

(1) To have his research supervised; Respondent agrees that prior to submission of an application for U.S. Public Health Service (PHS) support for a research project on which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agrees that he will not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agrees to maintain responsibility for compliance with the agreed upon supervision plan;

(2) that any institution employing him must submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(3) to exclude himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Acting Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8200.

Donald Wright,

Acting Director, Office of Research Integrity.

[FR Doc. 2015–13054 Filed 5–29–15; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the 2015 Hurricane Sandy Conference: Translating Research Into Practice

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) is hereby giving notice that ASPR will convene a Hurricane Sandy Conference: Translating Research into Practice public meeting on August 10–11, 2015. The purpose of the meeting is to broadly share, with interested stakeholders, outcomes of Hurricane Sandy recovery science research and training projects awarded under ASPR FOAs EP–HIT–13–001 and EP–HIT–14–001, Centers for Disease Control and Prevention (CDC) FOAs TP13–001 and OH13–002, and National Institute of Environmental Health Sciences (NIEHS) FOAs RFA–ES–13–008 and NOT–ES–13–003. Meeting participants will discuss opportunities to build a community of practice around Hurricane Sandy recovery research and the path forward for translating Hurricane Sandy recovery science research results into practice; highlight Hurricane Sandy recovery science grants as a model for disaster research science preparedness; and demonstrate the benefit of

Hurricane Sandy recovery research to the impacted communities.

DATES: The 2015 Hurricane Sandy Conference: Translating Research into Practice is scheduled on August 10 from 9 a.m. to 4:30 p.m. EST and on August 11 from 9 a.m. to 12:30 p.m. EST.

ADDRESSES: New York University's Kimmel Center for University Life, 60 Washington Square South, New York City, NY 10010. Registration is required for public attendance. Individuals who wish to attend the meeting should complete the registration via *www.PHE.gov/Research2Practice*.

FOR FURTHER INFORMATION CONTACT: Please contact *sciencepreparedness@hhs.gov* for additional information.

SUPPLEMENTARY INFORMATION:

Background: Shortly after Hurricane Sandy, ASPR, CDC, and NIEHS each funded a series of two-year research grants and training awards under the Disaster Relief Appropriations Act of 2013 (Pub. L. 113–2) that examine the long-term recovery of health systems, communities, and workers in the area of the country hardest hit by the storm. As the projects near completion, ASPR is hosting a public conference to share the research products and outcomes broadly with the impacted communities and other stakeholders.

Availability of Materials: The meeting agenda and materials will be posted on *www.PHE.gov/Research2Practice* prior to the meeting.

Registration for the Public Meeting: Information about registration for the meeting is available at *www.PHE.gov/Research2Practice.*

Dated: May 22, 2015.

Nicole Lurie,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2015–13050 Filed 5–29–15; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health: 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 Mental Health Special Emphasis Panel; Pilot Effectiveness Studies and Services Research Grants (R34).

Date: June 15, 2015.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Karen Gavin-Evans, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Boulevard, Room 6153, MSC 9606, Bethesda, MD 20892, 301–451–2356, *gavinevanskm@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: May 26, 2015.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–13049 Filed 5–29–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-day Comment Request; National Institute of Mental Health Recruitment and Milestone Reporting System (NIMH)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Mental Health (NIMH), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments And For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Keisha Shropshire, NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, OSPPC, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Rockville Pike, Bethesda, MD 20892, or call 301–443–4335 or Email your request, including your address to: *nimhprapubliccomments@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments received within 60 days of the date of this publication will receive fullest consideration.

Proposed Collection: The National Institute of Mental Health Recruitment Milestone Reporting System (NIMH); REVISION; OMB Control Number 0925–0697. National Institute of Mental Health, National Institutes of Health.

Need and Use of Information Collection: Recruitment Milestone Reporting (RMR) allows NIMH staff to monitor more accurately the required recruitment of participants in NIMH-sponsored clinical trials and other clinical research studies that plan to enroll 150 or more human subjects in a single study. Clinical studies can have difficulty recruiting, and accurate and timely reporting is the best way to ensure proper use of the grant funds. Investigators develop a recruitment plan that includes tri-yearly milestones for recruitment of the total study population, and for recruitment of racial and ethnic minority participants. Once recruitment is scheduled to begin, investigators report actual progress on recruitment milestones three times per year, by April 1, August 1, and December 1. Studies that fail to meet their milestones may be requested to provide interim monthly reports. The primary use of this information is to ensure that realistic recruitment targets are established from the onset of a project, and that these targets are met throughout the course of the research. By ensuring timely recruitment into clinical research studies, NIMH can reduce the need to extend timelines or supplement funds in order to complete the research project, and potentially

increase efficiency in our funding process.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2295.

ESTIMATED ANNUALIZED BURDEN HOURS

Form	Type of respondent	Number of respondents	Frequency of response	Average time per response (in hours)	Annual hour burden
NIMH Recruitment Milestone Reporting.	Principal Investigators/Research Assistant.	900	3	45/60	2025
NIMH Recruitment Milestone Monthly Report.	Principal Investigators/Research Assistant.	40	9	45/60	270

Dated: May 21, 2015.

Keisha L Shropshire,

Project Clearance Liaison, NIMH, NIH.

[FR Doc. 2015–13112 Filed 5–29–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); and on April 30, 2010 (75 FR 22809).

A notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at *http://beta.samhsa.gov/workplace.*

FOR FURTHER INFORMATION CONTACT: Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, Room 7–1051, One Choke Cherry Road, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. The ''Mandatory Guidelines for Federal Workplace Drug Testing Programs,'' as amended in the revisions listed above, requires strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on urine specimens for federal agencies.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that it has met minimum standards.

In accordance with the Mandatory Guidelines dated November 25, 2008 (73 FR 71858), the following HHS-certified laboratories and IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

HHS-Certified Instrumented Initial Testing Facilities: Dynacare Medical Laboratories, 6628 50th Street NW., Edmonton, AB Canada T6B 2N7, 780–784–1190.

HHS-Certified Laboratories: ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585–429–2264.

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615–255–2400, (Formerly: Aegis Sciences Corporation, Aegis Analytical Laboratories, Inc., Aegis Analytical Laboratories).

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823, (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.).

Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130, (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.).

Baptist Medical Center-Toxicology Laboratory, 11401 I–30, Little Rock, AR 72209–7056, 501–202–2783, (Formerly: Forensic Toxicology Laboratory Baptist Medical Center).

Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917.

DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800–235–4890.

Dynacare Medical Laboratories *, A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630.

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609.

Fortes Laboratories, Inc., 25749 SW Canyon Creek Road, Suite 600, Wilsonville, OR 97070, 503–486–1023.

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387.

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986, (Formerly: Roche Biomedical Laboratories, Inc.).

Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984, (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group).

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6339, (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center).

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845, (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.).

MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244.

MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295.

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088.

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661–322–4250/800–350–3515.

One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888–747–3774, (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory).

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942, (Formerly: Centinela Hospital Airport Toxicology Laboratory).

Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509–755–8991/800–541–7891x7.

Phamatech, Inc., 15175 Innovation Drive, San Diego, CA 92128, 888–635–5840, Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800–729–6432, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).

Quest Diagnostics Incorporated, 8401 Fallbrook Ave., West Hills, CA 91304, 818–737–6370, (Formerly: SmithKline Beecham Clinical Laboratories).

Redwood Toxicology Laboratory, 3700650 Westwind Blvd., Santa Rosa, CA 95403, 800–255–2159.

Southwest Laboratories, 4625 E. Cotton Center Boulevard, Suite 177, Phoenix, AZ 85040, 602–438–8507/800–279–0027.

STERLING Reference Laboratories, 2617 East L Street, Tacoma, Washington 98421, 800–442–0438.

U.S. Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085.

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register,** July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on April 30, 2010 (75 FR 22809). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Janine Denis Cook,

Chemist, Division of Workplace Programs, Center for Substance Abuse Prevention, SAMHSA.

[FR Doc. 2015–13083 Filed 5–29–15; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Intertek USA, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Intertek USA, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Intertek USA, Inc., has been approved to gauge and accredited to test petroleum and petroleum products for customs purposes for the next three years as of February 25, 2015.

DATES: *Effective Dates:* The accreditation and approval of Intertek USA, Inc., as commercial gauger and laboratory became effective on February 25, 2015. The next triennial inspection date will be scheduled for February 2018.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Intertek USA, Inc., 101 20th Street South, Texas City, TX 77590, has been approved to gauge and accredited to test petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Intertek USA, Inc., is approved for the following gauging procedures for petroleum and certain petroleum products set forth by the American Petroleum Institute (API):

API Chapters	Title
3	Tank gauging.
7	Temperature Determination.
8	Sampling.
12	Calculations.
17	Maritime Measurements.

Intertek USA, Inc., is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–01	ASTM D–287	Standard test method for API gravity of crude Petroleum & Petroleum products (Hydrometer Method).
27–02	ASTM D–1298	Standard Test Method for Density, Relative Density (Specific Gravity), or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method.
27–03	ASTM D–4006	Standard test method for water in crude oil by distillation.
27–04	ASTM D–95	Standard test method for water in petroleum products and bituminous materials by distillation.
27–05	ASTM D–4928	Standard test method for water in crude oils by Coulometric Karl Fischer Titration.
27–06	ASTM D–473	Standard test method for sediment in crude oils and fuel oils by the extraction method.
27–07	ASTM D–4807	Standard Test Method for Sediment in Crude Oil by Membrane Filtration.
27–08	ASTM D–86	Standard Test Method for Distillation of Petroleum Products.
27–11	ASTM D–445	Standard test method for kinematic viscosity of transparent and opaque liquids (and calculations of dynamic viscosity).
27–13	ASTM D–4294	Standard test method for sulfur in petroleum and petroleum products by energy-dispersive x-ray fluorescence spectrometry.
27–48	ASTM D–4052	Standard test method for density and relative density of liquids by digital density meter.
27–50	ASTM D–93	Standard test methods for flash point by Penske-Martens Closed Cup Tester.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/sites/default/files/documents/gaulist_3.pdf*

Dated: May 22, 2015.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2015–13071 Filed 5–29–15; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2559–15; DHS Docket No. USCIS–2013–0006]

RIN 1615–ZB38

Extension of the Designation of Somalia for Temporary Protected Status

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Through this Notice, the Department of Homeland Security (DHS) announces that the Secretary of Homeland Security (Secretary) is extending the designation of Somalia for Temporary Protected Status (TPS) for 18 months from September 18, 2015, through March 17, 2017.

The extension allows currently eligible TPS beneficiaries to retain TPS through March 17, 2017, so long as they otherwise continue to meet the eligibility requirements for TPS. The Secretary has determined that an extension is warranted because the conditions in Somalia that prompted the TPS designation continue to be met. There continues to be a substantial, but temporary, disruption of living conditions in Somalia due to ongoing armed conflict that would pose a serious threat to the personal safety of returning Somali nationals, as well as extraordinary and temporary conditions in the country that prevent Somali nationals from returning to Somalia in safety. The Secretary has also determined that permitting eligible Somali nationals to remain temporarily in the United States is not contrary to the national interest of the United States.

Through this Notice, DHS also sets forth procedures necessary for nationals of Somalia (or aliens having no nationality who last habitually resided in Somalia) to re-register for TPS and to apply for renewal of their Employment Authorization Documents (EADs) with U.S. Citizenship and Immigration Services (USCIS). Re-registration is limited to persons who have previously registered for TPS under the designation of Somalia and whose applications have been granted. Certain nationals of Somalia (or aliens having no nationality who last habitually resided in Somalia) who have not previously applied for TPS may be eligible to apply under the late initial registration provisions, if they meet: (1) At least one of the late initial filing criteria; and (2) all TPS eligibility criteria (including continuous residence in the United States since May 1, 2012, and continuous physical presence in the United States since September 18, 2012).

For individuals who have already been granted TPS under the Somalia designation, the 60-day re-registration period runs from June 1, 2015 through July 31, 2015. USCIS will issue new EADs with a March 17, 2017 expiration date to eligible Somalia TPS beneficiaries who timely re-register and apply for EADs under this extension.

DATES: The 18-month extension of the TPS designation of Somalia is effective September 18, 2015, and will remain in effect through March 17, 2017. The 60-day re-registration period runs from June 1, 2015 through July 31, 2015. (**Note:** It is important for re-registrants to timely re-register during this 60-day re-registration period and not to wait until their EADs expire.)

FOR FURTHER INFORMATION:

- For further information on TPS, including guidance on the application process and additional information on eligibility, please visit the USCIS TPS Web page at *http://www.uscis.gov/tps.* You can find specific information about this extension of Somalia's TPS designation by selecting ''TPS Designated Country: Somalia'' from the menu on the left of the TPS Web page.
- You can also contact the TPS Operations Program Manager at the Family and Status Branch, Service Center Operations Directorate, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue NW.,

Washington, DC 20529–2060; or by phone at (202) 272–1533 (this is not a toll-free number). Note: The phone number provided here is solely for questions regarding this TPS Notice. It is not for individual case status inquires.

- Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at 800–375–5283 (TTY 800–767–1833). Service is available in English and Spanish.
- Further information will also be available at local USCIS offices upon publication of this Notice.

SUPPLEMENTARY INFORMATION:

Table of Abbreviations

BIA—Board of Immigration Appeals
DHS—Department of Homeland Security
DOS—Department of State
EAD—Employment Authorization Document
FNC—Final Nonconfirmation
Government—U.S. Government
IDP—Internally Displaced Person
IJ—Immigration Judge
INA—Immigration and Nationality Act
OSC—U.S. Department of Justice, Office of Special Counsel for Immigration-Related Unfair Employment Practices
SAVE—USCIS Systematic Alien Verification for Entitlements Program
Secretary—Secretary of Homeland Security
TNC—Tentative Nonconfirmation
TPS—Temporary Protected Status
TTY—Text Telephone
UNHCR—Office of the United Nations High Commissioner for Refugees
USAID—U.S. Agency for International Development
USCIS—U.S. Citizenship and Immigration Services

What is Temporary Protected Status (TPS)?

- TPS is a temporary immigration status granted to eligible nationals of a country designated for TPS under the Immigration and Nationality Act (INA), or to eligible persons without nationality who last habitually resided in the designated country.
- During the TPS designation period, TPS beneficiaries are eligible to remain in the United States, may not be removed, and are authorized to work and obtain EADs, so long as they continue to meet the requirements of TPS.
- TPS beneficiaries may also be granted travel authorization as a matter of discretion.
- The granting of TPS does not result in or lead to permanent resident status.
- When the Secretary terminates a country's TPS designation, beneficiaries return to the same immigration status they maintained before TPS, if any (unless that status has since expired or been terminated), or to any other lawfully obtained immigration status they received while registered for TPS.

When was Somalia designated for TPS?

On September 16, 1991, the Attorney General designated Somalia for TPS based on extraordinary and temporary conditions. *See* 56 FR 46804 (Sept. 16, 1991). The initial designation was extended nine times based on determinations that the conditions warranting the designation continued to be met. On September 4, 2001, the Attorney General extended Somalia's TPS designation for a tenth time and redesignated Somalia for TPS. *See* 66 FR 46288 (Sept. 4, 2001). Under the 2001 redesignation, the Attorney General revised the date from which applicants had to show they had been ''continuously residing'' in and ''continuously physically present'' in the United States to September 4, 2001. Somalia's TPS designation was subsequently extended nine additional times, including on May 1, 2012, when the Secretary both extended and redesignated Somalia for TPS and added ongoing armed conflict as an additional basis for Somalia's TPS designation. Under the 2012 redesignation, the Secretary revised the ''continuous residence'' date to May 1, 2012, and the ''continuous physical presence'' date to September 18, 2012. *See* 77 FR 25723 (May 1, 2012). This announcement is the second extension of the TPS designation for Somalia since the 2012 extension and redesignation.

What authority does the Secretary of Homeland Security have to extend the designation of Somalia for TPS?

Section 244(b)(1) of the INA, 8 U.S.C. 1254a(b)(1), authorizes the Secretary, after consultation with appropriate agencies of the U.S. Government, to designate a foreign state (or part thereof) for TPS if the Secretary finds that certain country conditions exist.[1] The Secretary may then grant TPS to eligible nationals of that foreign state (or eligible aliens having no nationality who last habitually resided in that state). *See* INA section 244(a)(1)(A), 8 U.S.C. 1254a(a)(1)(A).

At least 60 days before the expiration of a country's TPS designation or extension, the Secretary, after consultation with appropriate Government agencies, must review the conditions in a foreign state designated for TPS to determine whether the conditions for the TPS designation continue to be met. *See* INA section 244(b)(3)(A), 8 U.S.C. 1254a(b)(3)(A). If the Secretary determines that a foreign state continues to meet the conditions for TPS designation, the designation may be extended for an additional period of 6, 12, or 18 months. *See* INA section 244(b)(3)(C), 8 U.S.C. 1254a(b)(3)(C). If the Secretary determines that the foreign state no longer meets the conditions for TPS designation, the Secretary must terminate the designation. *See* INA section 244(b)(3)(B), 8 U.S.C. 1254a(b)(3)(B).

Why is the Secretary extending the TPS designation for Somalia through March 17, 2017?

Over the past year, DHS and the Department of State (DOS) have continued to review conditions in Somalia. Based on this review and after consulting with DOS, the Secretary has determined that an 18-month extension is warranted because the conditions that led to the 2012 redesignation of Somalia for TPS—(1) ongoing armed conflict and (2) extraordinary and temporary conditions that prevent Somali nationals from returning to Somalia in safety—continue to exist, and that permitting eligible Somali nationals to remain temporarily in the United States is not contrary to the national interest of the United States.

Since President Hassan Sheikh Mohamud's inauguration in September 2012, the Federal Government of Somalia has made some progress in establishing government institutions, negotiating federal relationships with regional authorities, and attracting financial support from the international community. In spite of these political gains, instability and conflict persist throughout Somalia. A sustained military campaign against al-Shabaab in 2014 resulted in large numbers of civilian deaths and population displacement. Targeted attacks by al-Shabaab using suicide bombers and improvised explosive devices also resulted in significant civilian casualties. In October 2014, troops from the African Union Mission in Somalia, in coordination with the Somali National Army, successfully completed an offensive to liberate parts of south-central Somalia from al-Shabaab's control and to consolidate and expand the Somali government's security gains. Despite the offensive's success, al-

[1] As of March 1, 2003, in accordance with section 1517 of title XV of the Homeland Security Act of 2002, Public Law 107–296, 116 Stat. 2135, any reference to the Attorney General in a provision of the INA describing functions transferred from the Department of Justice to DHS ''shall be deemed to refer to the Secretary'' of Homeland Security. *See* 6 U.S.C. 557 (codifying section 1517 of the Homeland Security Act of 2002).

Shabaab maintains a stronghold in some rural areas of south central Somalia that surround urban centers, and continues to attack critical targets in Somalia and the region.

Even in government-controlled areas, al-Shabaab has demonstrated the capability to carry out attacks, with particular emphasis on targeting government facilities, the facilities and movements of foreign delegations, commercial establishments frequented by government officials, foreign nationals, the development and humanitarian community and the Somali diaspora. Al-Shabaab-planned and/or conducted assassinations, suicide bombings, and indiscriminate armed attacks in civilian populated areas were frequent in Somalia over the reporting period. Insecurity further persists as a result of inter-clan and inter-factional fighting, which flares up with little or no warning. The World Health Organization reported in June 2014 that violence and conflict continue to take a heavy toll on civilians in Somalia.

Somalia's ongoing complex emergency continues to shape the humanitarian situation within the country. While fragile gains have been made since the 2011–2012 famine that resulted in the deaths of an estimated 258,000 people, ongoing climatic conditions such as drought and flooding, coupled with insecurity, conflict, and an increase in food prices continue to result in significant humanitarian need. In September 2014, the U.S. Agency for International Development (USAID) reported that approximately 3.1 million people, or roughly 29 percent of the country's population, are experiencing some level of food insecurity, representing a 20 percent increase since January 2014 Malnutrition rates in Somalia remain among the highest in the world, with USAID reporting in September 2014 that an estimated 218,000 children under the age of 5 are acutely malnourished.

The Office of the United Nations High Commissioner for Refugees (UNHCR) stated in November 2014 that there are over 1.1 million internally displaced persons (IDPs) in Somalia. In addition to those internally displaced, UNHCR also noted that more than 950,000 Somalis have sought refuge in neighboring countries in the Horn of Africa and in Yemen. USAID noted that forced evictions, drought, conflict, and lack of livelihoods have displaced 130,000 Somalis since January 2014, and approximately 369,000 IDPs live in makeshift camps in Mogadishu. UNHCR reports that IDPs in Somalia often live in crowded settlements, lack adequate protection, and face forced evictions, discrimination, and gender-based violence.

The security situation remains volatile, and the risks associated with humanitarian aid work are high due to insecurity as well as direct and indirect attacks on humanitarian personnel and assets. According to the United Nations, from January to September 2014, there were 40 violent incidents against aid workers. Armed groups also made several attempts to loot relief food and disrupt food distributions. Al-Shabaab maintains control over some key supply routes, hampering commercial activities and the delivery of humanitarian assistance.

Many critical services were unavailable to Somalis because of insufficient resources and the government's limited capacity to deliver essential services and provide basic security. For instance, the health sector was unable to provide a functional system of primary or secondary health clinics, and the justice sector lacked the capacity to effectively administer justice or enforce the law.

Based upon this review and after consultation with appropriate Government agencies, the Secretary finds that:

- The conditions that prompted the May 1, 2012 redesignation of Somalia for TPS continue to be met. *See* INA section 244(b)(1)(A) and (C), (b)(3)(A) and (C); 8 U.S.C. 1254a(b)(1)(A) and (C), (b)(3)(A) and (C).
- There continues to be an ongoing armed conflict in Somalia and, due to such conflict, requiring the return of Somali nationals would pose a serious threat to their safety. *See* INA section 244(b)(1)(A), 8 U.S.C. 1254a(b)(1)(A).
- There continue to be extraordinary and temporary conditions in Somalia that prevent Somali nationals from returning to Somalia in safety. *See* INA section 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C).
- It is not contrary to the national interest of the United States to permit Somalis (and persons who have no nationality who last habitually resided in Somalia) who meet the eligibility requirements of TPS to remain in the United States temporarily. *See* INA section 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C).
- The designation of Somalia for TPS should be extended for an additional 18-month period from September 18, 2015, through March 17, 2017. *See* INA section 244(b)(3)(C), 8 U.S.C. 1254a(b)(3)(C).
- There are approximately 270 current Somalia TPS beneficiaries who are expected to file for re-registration under the extension.

Notice of Extension of the TPS Designation of Somalia

By the authority vested in me as Secretary under INA section 244, 8 U.S.C. 1254a, I have determined, after consultation with the appropriate Government agencies, that the conditions that prompted the redesignation of Somalia for TPS on May 1, 2012, continue to be met. *See* INA section 244(b)(3)(A), 8 U.S.C. 1254a(b)(3)(A). On the basis of this determination, I am extending the designation of Somalia for TPS for 18 months from September 18, 2015 through March 17, 2017. *See* INA section 244(b)(1)(A) and (C), (b)(2); 8 U.S.C. 1254a(b)(1)(A) and (C), (b)(2).

Jeh Charles Johnson,

Secretary.

Required Application Forms and Application Fees To Register or Re-Register for TPS

To register or re-register for TPS based on the designation of Somalia, an applicant must submit each of the following two applications:

1. Application for Temporary Protected Status (Form I–821).

- If you are filing an application for late initial registration, you must pay the fee for the Application for Temporary Protected Status (Form I–821). *See* 8 CFR 244.2(f)(2) and 244.6 and information on late initial filing on the USCIS TPS Web page at *http://www.uscis.gov/tps.*
- If you are filing an application for re-registration, you do not need to pay the fee for the Application for Temporary Protected Status (Form I–821). *See* 8 CFR 244.17. and

2. Application for Employment Authorization (Form I–765).

- If you are applying for late initial registration and want an EAD, you must pay the fee for the Application for Employment Authorization (Form I–765) only if you are age 14 through 65. No fee for the Application for Employment Authorization (Form I–765) is required if you are under the age of 14 or are 66 and older and applying for late initial registration.
- If you are applying for re-registration, you must pay the fee for the Application for Employment Authorization (Form I–765) only if you want an EAD, regardless of age.
- You do not pay the fee for the Application for Employment Authorization (Form I–765) if you are not requesting an EAD, regardless of whether you are applying for late initial registration or re-registration.

You must submit both completed application forms together. If you are unable to pay for the Application for Employment Authorization (Form I–765) and/or biometrics fee, you may apply for a fee waiver by completing a Request for Fee Waiver (Form I–912) or submitting a personal letter requesting a fee waiver, and by providing satisfactory supporting documentation. For more information on the application forms and fees for TPS, please visit the USCIS TPS Web page at *http://www.uscis.gov/tps.* Fees for the Application for Temporary Protected Status (Form I–821), the Application for Employment Authorization (Form I–765), and biometric services are also described in 8 CFR 103.7(b)(1)(i).

Biometric Services Fee

Biometrics (such as fingerprints) are required for all applicants 14 years of age or older. Those applicants must submit a biometric services fee. As previously stated, if you are unable to pay for the biometric services fee, you may apply for a fee waiver by completing a Request for Fee Waiver (Form I–912) or by submitting a personal letter requesting a fee waiver, and providing satisfactory supporting documentation. For more information on the biometric services fee, please visit the USCIS Web site at *http://www.uscis.gov.* If necessary, you may be required to visit an Application Support Center to have your biometrics captured.

Re-Filing a Re-Registration TPS Application After Receiving a Denial of a Fee Waiver Request

USCIS urges all re-registering applicants to file as soon as possible within the 60-day re-registration period so that USCIS can process the applications and issue EADs promptly. Filing early will also allow those applicants who may receive denials of their fee waiver requests to have time to re-file their applications before the re-registration deadline. If, however, an applicant receives a denial of his or her fee waiver request and is unable to re-file by the re-registration deadline, the applicant may still re-file his or her application. This situation will be reviewed to determine whether the applicant has established good cause for late re-registration. However, applicants are urged to refile within 45 days of the date on their USCIS fee waiver denial notice, if at all possible. *See* INA section 244(c)(3)(C), 8 U.S.C. 1254a(c)(3)(C); 8 CFR 244.17(c). For more information on good cause for late re-registration, visit the USCIS TPS Web page at *http://www.uscis.gov/tps.* **Note:** As previously stated, although a re-registering TPS beneficiary age 14 and older must pay the biometric services fee (but not the initial TPS application fee) when filing a TPS re-registration application, the applicant may decide to wait to request an EAD, and therefore not pay the Application for Employment Authorization (Form I–765) fee, until after USCIS has approved the individual's TPS re-registration, if he or she is eligible. If you choose to do this, you would file the Application for Temporary Protected Status (Form I–821) with the fee and the Application for Employment Authorization (Form I–765) without the fee and without requesting an EAD.

Mailing Information

Mail your application for TPS to the proper address in Table 1.

TABLE 1—MAILING ADDRESSES

If. . .	Mail to. . .
You are applying through the U.S. Postal Service	USCIS: Attn: TPS Somalia, P.O. Box 6943, Chicago, IL 60680–6943.
You are using a non-U.S. Postal Service delivery service	USCIS: Attn: TPS Somalia, 131 S. Dearborn, 3rd Floor, Chicago, IL 60603–5517.

If you were granted TPS by an Immigration Judge (IJ) or the Board of Immigration Appeals (BIA), and you wish to request an EAD, or are re-registering for the first time following a grant of TPS by an IJ or the BIA, please mail your application to the appropriate address in Table 1. Upon receiving a Notice of Action (Form I–797) from USCIS, please send an email to the appropriate USCIS Service Center handling your application providing the receipt number and stating that you submitted a re-registration and/or request for an EAD based on an IJ/BIA grant of TPS. Upon receiving a Notice of Action (Form I–797) from USCIS, please send an email to *TPSijgrant.vsc@uscis.dhs.gov* with the receipt number and state that you submitted a re-registration and/or request for an EAD based on an IJ/BIA grant of TPS. You can find detailed information on what further information you need to email and the email addresses on the USCIS TPS Web page at *http://www.uscis.gov/tps.*

E-Filing

You cannot electronically file your application when re-registering or submitting a late initial registration for Somalia TPS. Please mail your application to the mailing address listed in Table 1.

Employment Authorization Document (EAD)

May I request an interim EAD at my local USCIS office?

No. USCIS will not issue interim EADs to TPS applicants and re-registrants at local offices.

Am I eligible to receive an automatic 6-month extension of my current EAD through March 17, 2016?

No. Previously issued EADs will not be automatically extended. You must apply for a new EAD during the 60-day re- registration period. Failure to file your TPS application during the re-registration period without good cause may result in gaps in work authorization. DHS strongly encourages you to apply as early as possible within the re-registration period to avoid a gap in your employment authorization.

When hired, what documentation may I show to my employer as proof of employment authorization and identity when completing Employment Eligibility Verification (Form I–9)?

You can find a list of acceptable document choices on the ''Lists of Acceptable Documents'' for Employment Eligibility Verification (Form I–9). You can find additional detailed information on the USCIS I–9 Central Web page at *http://www.uscis.gov/I-9Central.* Employers are required to verify the identity and employment authorization of all new employees by using Employment Eligibility Verification (Form I–9). Within 3 days of hire, an employee must present proof of identity and employment authorization to his or her employer.

You may present any document from List A (reflecting both your identity and employment authorization) or one

document from List B (reflecting identity) together with one document from List C (reflecting employment authorization). You may present an acceptable receipt for List A, List B, or List C documents as described in the Form I–9 Instructions. An EAD is an acceptable document under ''List A.'' Employers may not reject a document based on a future expiration date.

What documentation may I show my employer if I am already employed but my current TPS-related EAD is set to expire?

At the time of expiration, you must present any document from List A or any document from List C on Employment Eligibility Verification (Form I–9) to re-verify employment authorization, or an acceptable List A or List C receipt described in the Form I–9 instructions. Your employer is required to re-verify on Employment Eligibility Verification (Form I–9) the employment authorization of current employees upon the expiration of a TPS-related EAD. Your employer should use either section 3 of the Employment Eligibility Verification (Form I–9) originally completed for the employee or, if this section has already been completed or if the version of Employment Eligibility Verification (Form I–9) is no longer valid, complete section 3 of a new Employment Eligibility Verification (Form I–9) using the most current version. Note that your employer may not specify which List A or List C document employees must present, and cannot reject an acceptable receipt.

USCIS anticipates that it will be able to process and issue new EADs for existing TPS Somalia beneficiaries before their current EADs expire on September 17, 2015. However, re-registering beneficiaries are encouraged to file as early as possible within the 60-day re-registration period to help ensure that they receive their EADs promptly.

Can my employer require that I produce any other documentation to prove my status, such as proof of my Somali citizenship?

No. When completing Employment Eligibility Verification (Form I–9), including re-verifying employment authorization, employers must accept any documentation that appears on the ''Lists of Acceptable Documents'' for Employment Eligibility Verification (Form I–9) that reasonably appears to be genuine and that relates to you or an acceptable List A, List B, or List C receipt. Employers may not request documentation that does not appear on the ''Lists of Acceptable Documents.'' Therefore, employers may not request proof of Somali citizenship when completing Employment Eligibility Verification (Form I–9) for new hires or reverifying the employment authorization of current employees. Refer to the Note to Employees section of this Notice for important information about your rights if your employer rejects lawful documentation, requires additional documentation, or otherwise discriminates against you based on your citizenship or immigration status, or your national origin.

Note to All Employers

Employers are reminded that the laws requiring proper employment eligibility verification and prohibiting unfair immigration-related employment practices remain in full force. This Notice does not supersede or in any way limit applicable employment verification rules and policy guidance, including those rules setting forth reverification requirements. For general questions about the employment eligibility verification process, employers may call USCIS at 888–464–4218 (TTY 877–875–6028) or email USCIS at *I-9Central@dhs.gov.* Calls and emails are accepted in English and many other languages. For questions about avoiding discrimination during the employment eligibility verification process, employers may also call the U.S. Department of Justice, Civil Rights Division, Office of Special Counsel for Immigration-Related Unfair Employment Practices (OSC) Employer Hotline at 800–255–8155 (TTY 800–237–2515), which offers language interpretation in numerous languages, or email OSC at *osccrt@usdoj.gov.*

Note to Employees

For general questions about the employment eligibility verification process, employees may call USCIS at 888–897–7781 (TTY 877–875–6028) or email at *I-9Central@dhs.gov.* Calls are accepted in English and many other languages. Employees or applicants may also call the U.S. Department of Justice, Civil Rights Division, Office of Special Counsel for Immigration-Related Unfair Employment Practices (OSC) Worker Information Hotline at 800–255–7688 (TTY 800–237–2515) for information regarding employment discrimination based upon citizenship status, immigration status, or national origin, or for information regarding discrimination related to Employment Eligibility Verification (Form I–9) and E-Verify. The OSC Worker Information Hotline provides language interpretation in numerous languages.

To comply with the law, employers must accept any document or combination of documents from the Lists of Acceptable Documents if the documentation reasonably appears to be genuine and to relate to the employee, or an acceptable List A, List B, or List C receipt described in the Employment Eligibility Verification (Form I–9) Instructions. Employers may not require extra or additional documentation beyond what is required for Employment Eligibility Verification (Form I–9) completion. Further, employers participating in E-Verify who receive an E-Verify case result of ''Tentative Nonconfirmation'' (TNC) must promptly inform employees of the TNC and give such employees an opportunity to contest the TNC. A TNC case result means that the information entered into E-Verify from Employment Eligibility Verification (Form I–9) differs from records available to DHS or the Social Security Administration.

Employers may not terminate, suspend, delay training, withhold pay, lower pay or take any adverse action against an employee based on the employee's decision to contest a TNC or because the case is still pending with E-Verify. A Final Nonconfirmation (FNC) case result is received when E-Verify cannot verify an employee's employment eligibility. An employer may terminate employment based on a case result of FNC. Work-authorized employees who receive an FNC may call USCIS for assistance at 888–897–7781 (TTY 877–875–6028). An employee that believes he or she was discriminated against by an employer in the E-Verify process based on citizenship or immigration status, or based on national origin, may contact OSC's Worker Information Hotline at 800–255–7688 (TTY 800–237–2515). Additional information about proper nondiscriminatory Employment Eligibility Verification (Form I–9) and E-Verify procedures is available on the OSC Web site at *http://www.justice.gov/crt/about/osc/* and the USCIS Web site at *http://www.dhs.gov/E-verify.*

Note Regarding Federal, State, and Local Government Agencies (Such as Departments of Motor Vehicles)

While Federal Government agencies must follow the guidelines laid out by the Federal Government, State and local government agencies establish their own rules and guidelines when granting certain benefits. Each State may have different laws, requirements, and determinations about what documents you need to provide to prove eligibility for certain benefits. Whether you are applying for a Federal, State, or local

government benefit, you may need to provide the government agency with documents that show you are a TPS beneficiary and/or show you are authorized to work based on TPS. Examples are:

(1) Your unexpired EAD;

(2) A copy of your Application for Temporary Protected Status Notice of Action (Form I–797) for this re-registration; and/or

(3) A copy of your past or current Application for Temporary Protected Status Approval Notice (Form I–797), if you received one from USCIS.

Check with the government agency regarding which document(s) the agency will accept. You may also provide the agency with a copy of this **Federal Register** Notice.

Some benefit-granting agencies use the USCIS Systematic Alien Verification for Entitlements Program (SAVE) to verify the current immigration status of applicants for public benefits. If such an agency has denied your application based solely or in part on a SAVE response, the agency must offer you the opportunity to appeal the decision in accordance with the agency's procedures. If the agency has received and acted upon or will act upon a SAVE verification and you do not believe the response is correct, you may make an InfoPass appointment for an in-person interview at a local USCIS office. Detailed information on how to make corrections, make an appointment, or submit a written request to correct records under the Freedom of Information Act can be found at the SAVE Web site at *http://www.uscis.gov/save,* then by choosing ''How to Correct Your Records'' from the menu on the right.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FW–HQ–WSFR–2015–N110; FVWF941009000007B–XXX–FF09W11000; FVWF51100900000–XXX–FF09W11000]

Proposed Information Collection; Wildlife and Sport Fish Grants and Cooperative Agreements

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; revision and request for comments.

SUMMARY: We (U.S. Fish and Wildlife Service) published a notice on May 11, 2015, announcing our intention to ask the Office of Management to renew approval for the information collection (IC) described below. We are revising that notice to: (1) Provide the estimated date for States to begin entering information into the new electronic system (Wildlife Tracking and Reporting Actions for the Conservation of Species); (2) revise the burden for reporting the information; and (3) extend the comment period. As required by the Paperwork Reduction Act of 1995 and as part of our continuing efforts to reduce paperwork and respondent burden, we invite the general public and other Federal agencies to take this opportunity to comment on this IC. This IC is scheduled to expire on September 30, 2015. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: To ensure that we are able to consider your comments on this IC, we must receive them by July 31, 2015.

ADDRESSES: Send your comments on this IC to the Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or *hope_grey@fws.gov* (email). Please include ''1018–0109'' in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this IC, contact Hope Grey at *hope_grey@fws.gov* (email) or 703–358–2482 (telephone).

SUPPLEMENTARY INFORMATION:

I. Abstract

The Wildlife and Sport Fish Restoration Program (WSFR), U.S. Fish and Wildlife Service, administers the following financial assistance programs in whole or in part. We award most financial assistance as grants, but cooperative agreements are possible if the Federal Government will be substantially involved in carrying out the project. You can find a description of most programs in the Catalog of Federal Domestic Assistance (CFDA).

Program	CFDA No.	Authority	Implementing regulations
Clean Vessel Act	15.616	16 U.S.C. 777g(c)	50 CFR 85.
Coastal Wetlands Planning, Protection, and Restoration Act.	15.614	16 U.S.C. 3951–3956	50 CFR 84.
Cooperative Endangered Species Conservation Fund	15.615	16 U.S.C. 1531 *et seq*	50 CFR 81.
Everglades Restoration *	None	Pub. L. 104–127; 16 U.S.C. 460 l–4 thru l–11	None.
Fish and Wildlife Coordination and Assistance Programs (Generic).	15.664		None.
Fisheries Restoration and Irrigation Mitigation *	None	16 U.S.C. 777	None.
Highlands Conservation Program	15.667		None.
Hunter Education and Safety	15.626	16 U.S.C. 669h–1	50 CFR 80.
Landowner Incentive *	15.633	Pub. L. 110–5	None.
Multistate Conservation Grants	15.628	16 U.S.C. 669h–2; 16 U.S.C. 777m	None.
National Outreach and Communication	15.653	16 U.S.C. 777g(d)	None.
Research Grants (Generic)	15.650	16 U.S.C. 753a; 16 U.S.C. 460 (l–4–thru l–11); 16 U.S.C. 1531–1543.	None.
Service Training and Technical Assistance (Generic Training).	15.649	16 U.S.C. 661 and 16 U.S.C. 742f	None.
Sport Fish Restoration	15.605	16 U.S.C. 777–777n (except 777e–1)	50 CFR 80.
Sportfishing and Boating Safety Act (Boating Infrastructure Grants).	15.622	16 U.S.C. 777g and g–1	50 CFR 86.
State Wildlife Grants	15.634	Pub. L. 110–329	None.
Tribal Landowner Incentive *	15.638	Pub. L. 110–5	None.
Tribal Wildlife Grants	15.639	Pub. L. 110–329	None.
Wildlife Conservation and Restoration *	15.625	16 U.S.C. 669b and 669c	None.
Wildlife Restoration	15.611	16 U.S.C. 669–669k	50 CFR 80.

* Program has open grants, but no new funding.

Authorities and implementing regulations establish the purposes of the grant programs and the types of projects to be funded. Some list eligibility criteria as well as activities ineligible for funding. The authorities and implementing regulations for the competitive programs establish preferences or ranking factors for the selection of projects to be funded. These legal requirements make it essential for an awarding agency to have certain information so that it funds only eligible projects, and, in the case of competitive programs, to select those projects that will result in the greatest return on the Federal investment.

Some grants are mandatory and receive funds according to a formula set by law or policy. Other grants are discretionary, and we award them based on a competitive process. Mandatory grant recipients must give us specific, detailed project information during the application process so that we can ensure that projects are eligible for the mandatory funding, are substantial in character and design, and comply with all applicable Federal laws. All grantees must submit financial and performance reports that contain information necessary for us to track costs and accomplishments.

In February 2014, OMB approved our request to use a new electronic system (Wildlife Tracking and Reporting Actions for the Conservation of Species (Wildlife TRACS)) to collect application and performance reporting information on our grant programs. OMB assigned OMB Control No. 1018–0156, which expires February 28, 2017. Wildlife TRACS allows us to take advantage of newer technology and gives applicants direct access to enter project information that can be used to submit an application through *http://www.grants.gov.* Grantees can also report performance accomplishments in Wildlife TRACS. We are including the use of Wildlife TRACS and the collection of additional information in this revision to OMB Control No. 1018–0109. If OMB approves this revision, we will discontinue OMB Control No. 1018–0156.

We may require all States to directly enter project information and performance reporting into Wildlife TRACS by October 1, 2016. We continue to offer training and support to States on entering information into the new system. When States fully engage in directly entering all application and project performance reporting into Wildlife TRACS, we expect there will be a reduction in the burden to report the information. States will become more adept with experience, and efficiencies of the electronic system will be realized starting in the second full year of use. A majority of WSFR-administered projects are continuations of similar actions and/or at the same locations. Wildlife TRACS is designed to ease the administrative burden of applying for and reporting on grants for projects that fall into these parameters. The table below reflects the burden reduction that we expect over the next 3 years. Not all grantees will directly enter information into Wildlife TRACS. We will enter information when we determine the grantee or the program is such that it is not efficient or in the best interest of the program to have grantees enter information.

To apply for financial assistance funds, you must submit an application that describes in substantial detail project locations, benefits, funding, and other characteristics. Materials to assist applicants in formulating project proposals are available on Grants.gov. We use the application to determine:

- Eligibility.
- Scale of resource values or relative worth of the project.
- If associated costs are reasonable and allowable.
- Potential effect of the project on environmental and cultural resources.
- How well the proposed project will meet the purposes of the program's establishing legislation.
- If the proposed project is substantial in character and design.
- For competitive programs, how the proposed project addresses ranking criteria.

Persons or entities receiving grants must submit periodic performance reports that contain information necessary for us to track costs and accomplishments.

In addition to the information currently collected under OMB Control No. 1018–0109, we will collect the following additional information currently approved under OMB Control No. 1018–0156:

For mandatory grant program applications and amendments:

- Geospatial entry of project location.
- Project status (active, completed, etc.).
- Project leader contact information.
- Partner information.
- Objectives, including output measures and desired future values.
- Plan information (for projects connected to plans).

For all WSFR grant program projects and reports:

- The information above, as applicable to the approved grant.
- Public description.
- Action status (active, completed, etc.).
- Summary trend information, as applicable.
- Estimated costs, by action (non-auditable).
- Effectiveness measures (initially for State Wildlife Grants).

For real property acquisition projects, information related to:

- Transactions, such as dates, method of transfer, title holder, and seller.
- Identifiers, such as State and Federal Record ID, parcel number, and property name.
- Values such as appraised value, purchase price and other cost information, and acres or acre feet.
- Encumbrances.
- Partners.

II. Data

OMB Control Number: 1018–0109.

Title: Wildlife and Sport Fish Grants and Cooperative Agreements, 50 CFR 80, 81, 84, 85, and 86.

Service Form Number: None.

Type of Request: Revision of a currently approved collection.

Description of Respondents: States; the Commonwealths of Puerto Rico and the Northern Mariana Islands; the District of Columbia; the territories of Guam, U.S. Virgin Islands, and American Samoa; federally recognized tribal governments; institutions of higher education; and nongovernmental organizations.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: We require applications annually for new grants. We require amendments on occasion when key elements of a project change. We require quarterly and final performance reports in the National Outreach and Communication Program and annual and final performance reports in the other programs. We may require more frequent reports under the conditions stated at 2 CFR 200.205 and 2 CFR 200.207.

Activity	Number of respondents	Number of responses	Completion time per response	Total annual burden hours
Initial application (project narrative)	200	2,500	37	92,500

Activity	Number of respondents	Number of responses	Completion time per response	Total annual burden hours
Revision of Award Terms (Amendment)	150	1,500	3	4,500
Performance Reports	200	3,500	8	28,000
Totals	550	7,500	.....	125,000

III. Comments

We invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this IC. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: May 27, 2015.

Tina A. Campbell,

Chief, Division of Policy, Performance, and Management Programs, U.S. Fish and Wildlife Service.

[FR Doc. 2015–13089 Filed 5–29–15; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCO956000 L14400000.BJ0000]

Notice of Filing of Plats of Survey; Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey; Colorado.

SUMMARY: The Bureau of Land Management (BLM) Colorado State Office is publishing this notice to inform the public of the official filing of the survey plat listed below. The plat will be available for viewing at *http://www.glorecords.blm.gov.*

DATES: The plat described in this notice was filed on April 30, 2015.

ADDRESSES: BLM Colorado State Office, Cadastral Survey, 2850 Youngfield Street, Lakewood, CO 80215–7093.

FOR FURTHER INFORMATION CONTACT: Randy Bloom, Chief Cadastral Surveyor for Colorado, (303) 239–3856. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The supplemental plat of sections 21, 22, 27, and 28 in Township 42 North, Range 9 West, New Mexico Meridian, Colorado, was accepted on April 29, 2015, and filed on April 30, 2015.

Randy Bloom,

Chief Cadastral Surveyor for Colorado.

[FR Doc. 2015–13092 Filed 5–29–15; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCOF02000.L16100000.DP0000]

Notice of Intent To Prepare the Eastern Colorado Resource Management Plan and an Associated Environmental Impact Statement for the Royal Gorge Field Office, Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended (FLPMA), the Bureau of Land Management (BLM) Royal Gorge Field Office (RGFO), Cañon City, Colorado, intends to prepare a Resource Management Plan (RMP) with an associated Environmental Impact Statement (EIS). By this notice, the BLM is announcing the beginning of the scoping process to solicit public comments and identify issues. The RMP will replace the existing 1996 Royal Gorge RMP and the 1986 Northeast RMP. The BLM is also soliciting resource information for coal and other resources in the planning area.

DATES: This notice initiates the public scoping process for the RMP with an associated EIS. Comments on issues may be submitted in writing until July 31, 2015. The date(s) and location(s) of any scoping meetings will be announced at least 15 days in advance through local media, newspapers and the BLM Web site at: *http://www.blm.gov/co/st/en/fo/rgfo.html.* In order to be included in the Draft EIS, all comments must be received prior to the close of the 60-day scoping period or 15 days after the last public meeting, whichever is later. We will provide additional opportunities for public participation upon publication of the Draft RMP/EIS.

ADDRESSES: You may submit comments on issues and planning criteria related to the RGFO RMP/EIS by any of the following methods:

- Web site: *http://www.blm.gov/co/st/en/fo/rgfo.html.*
- Email: *rgfo_rmp_comments@blm.gov.*
- Fax: 719–269–8599.
- Mail: BLM Royal Gorge Field Office, 3028 E. Main St., Cañon City, CO 81212.

Documents pertinent to this proposal may be examined at the RGFO at the address above.

FOR FURTHER INFORMATION CONTACT: John Smeins, RMP Project Manager; telephone, 719–269–8581; BLM Royal Gorge Field Office (see **ADDRESSES** section); email, *rgfo_rmp_comments@blm.gov.* Contact Mr. Smeins to add your name to our mailing list. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This document provides notice that the BLM intends to prepare an RMP with an associated EIS for the RGFO, announces the beginning of the scoping process, and seeks public input on issues and planning criteria. The RMP will be titled ''Eastern Colorado RMP''. The planning area is located in 38 counties in eastern Colorado and encompasses approximately 668,000 surface acres of public land and 6.6 million acres of mineral estate. A Master Leasing Plan for the South Park area will be considered. The purpose of the public scoping process is to determine relevant issues that will influence the scope of the environmental analysis, seek nominations for Areas of Critical Environmental Concern (ACEC), and guide the planning process. The following preliminary issues to be analyzed in the planning area were identified by BLM personnel; Federal, State and local agencies; and other stakeholders:

- Identifying authorized and permitted land uses for growing populations and expanding urban interface with consideration for community interests and needs;
- Addressing increasing numbers and types of human activities and uses;
- Managing vegetative and water resources, terrestrial and aquatic habitat, and special management areas (ACEC nominations), while sustaining biological diversity and native species populations;
- Managing minerals, and renewable and nonrenewable energy resources;
- Considering land tenure adjustments, split estate, areas recommended for withdrawal, and utility/energy corridors;
- Managing and protecting cultural, historical, and paleontological resources, and Native American heritage resources; and
- Considering opportunities for appropriate regional mitigation, including identifying priority areas for both conservation and development.

Preliminary planning criteria include:

- Complying with FLPMA, NEPA and other applicable laws and regulations;
- Encouraging public participation and collaboration;
- Consulting with American Indian tribes and strategies for protecting recognized sacred areas, Traditional Cultural Properties, and traditional use areas;
- Establishing collaborative partnerships with cooperating agencies and other interested groups, agencies, and individuals;
- Incorporating the BLM Colorado Standards for Public Land Health;
- Continuing management of Wilderness Study Areas under the Interim Management Policy for Lands under Wilderness Review until Congress acts on a designation or releases lands from consideration;
- Recognizing valid existing land use and ownership rights;
- Including adaptive management criteria to explore alternative ways to meet management objectives in the future;
- Complying with existing plans and policies of adjacent local, State and Federal agencies and local American Indian tribes; and
- Using the best available scientific information and research where practicable for the planning effort.

You may submit comments on issues and planning criteria in writing to the BLM at any public scoping meeting, or you may submit them to the BLM using one of the methods listed in the **ADDRESSES** section above. To be most helpful, you should submit comments by the close of the 60-day scoping period or within 15 days after the last public meeting, whichever is later. 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.

The BLM will evaluate identified issues to be addressed in the plan, and will place them into one of three categories:

1. Issues to be resolved in the plan;
2. Issues to be resolved through policy or administrative action; or
3. Issues beyond the scope of this plan.

The BLM will provide an explanation in the Draft RMP/Draft EIS as to why an issue was placed in category two or three. The public is also encouraged to help identify any management questions and concerns that should be addressed in the plan. The BLM will work collaboratively with interested parties to identify management decisions that are best suited to local, regional, and national needs and concerns.

Parties interested in leasing and development of Federal coal in the planning area should provide coal resource data for their area(s) of interest. Specifically, information is requested on the location, quality and quantity of Federal coal with development potential, and on surface resource values related to the 20 coal mining unsuitability criteria described in 43 CFR part 3461. This information will be used for any necessary updating of coal screening determination (43 CFR 3420.1–4) in the Decision Area and in the environmental analysis for the RMP. Proprietary data marked as confidential may be submitted in response to this call for coal information. Please submit all proprietary information to the address listed above. The BLM will treat submissions marked as ''Confidential'' in accordance with applicable laws and regulations governing the confidentiality of such information.

The BLM is also requesting nominations of areas for ACEC designation. To be considered as a potential ACEC, an area must meet the criteria of relevance and importance as established and defined in 43 CFR 1610.7–2. Nominations must include descriptive materials, detailed maps and evidence supporting the relevance and importance of the resource or area. There are currently nine ACECs within the RGFO boundary designated by the 1996 Royal Gorge RMP: Arkansas Canyonlands, Beaver Creek, Browns Canyon, Cucharas Canyon, Droney Gulch, Garden Park, Grape Creek, Mosquito Pass and Phantom Canyon. All ACEC nominations within the planning area will be evaluated through the RMP process.

The BLM will use NEPA public participation requirements to assist the agency in satisfying the public involvement requirements under Section 106 of the National Historic Preservation Act (NHPA), 16 U.S.C. 470(f), pursuant to 36 CFR 800.2(d)(3). The information about historic and cultural resources within the area potentially affected by the proposed action will assist the BLM in identifying and evaluating impacts to such resources in the context of both NEPA and Section 106 of the NHPA.

The BLM will consult with Indian tribes on a government-to-government basis in accordance with Executive Order 13175 and other policies. Tribal interests, including impacts on Indian trust assets and potential impacts to cultural resources, will be given due consideration. Federal, State and local agencies, along with tribes and other stakeholders that may be interested in or affected by the proposed action that the BLM is evaluating, are invited to participate in the scoping process and, if eligible, may request or be requested by the BLM to participate in the development of the environmental analysis as a cooperating agency.

The BLM will use an interdisciplinary approach to develop the plan to

consider the variety of resource issues and concerns identified. Specialists with expertise in the following disciplines will be involved in the planning process: Wildlife; threatened and endangered species; vegetation; riparian and wetlands; soils; invasive and noxious weeds; rangeland management; fire ecology and management; cultural resources and Native American interests; hydrology; geology and minerals; lands and realty; recreation; visual resource management; public safety; law enforcement; and Geographic Information Systems.

Ruth Welch,

BLM Colorado State Director.

Authority: 40 CFR 1501.7, 43 CFR 1610.2

[FR Doc. 2015–13060 Filed 5–29–15; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NER–MAMC–16754; PPNCNACEN0, PPMPSAS1Z.Y00000]

Request for Nominations for the Mary McLeod Bethune Council House National Historic Site Advisory Commission

AGENCY: National Park Service, Interior.

ACTION: Request for nominations.

SUMMARY: The National Park Service, U.S. Department of the Interior, is seeking nominations for the Mary McLeod Bethune Council House National Historic Site Advisory Commission (Commission). The purpose of the Commission is to advise the Secretary of the Interior in the implementation of a general management plan for the Mary McLeod Bethune Council House National Historic Site.

DATES: Written nominations must be postmarked by July 1, 2015.

ADDRESSES: Send nominations to Gopaul Noojibail, Superintendent, National Capital Parks-East, Attention: Vicky Gammon, Chief of Staff, National Capital Parks-East, National Park Service, 1900 Anacostia Drive SW., Washington, DC 20020, telephone (202) 690–5193, or email *vicky_gammon@nps.gov.*

FOR FURTHER INFORMATION CONTACT: Vicky Gammon, Chief of Staff, National Capital Parks-East, National Park Service, 1900 Anacostia Drive SW., Washington, DC 20020, telephone (202) 690–5193, or email *NACE_Superintendent@nps.gov.*

SUPPLEMENTARY INFORMATION: The Mary McLeod Bethune Council House National Historic Site Advisory Commission was authorized on December 11, 1991, by Public Law 102–211 (16 U.S.C. 461 note), for the purpose of advising the Secretary of the Interior in the implementation a general management plan for the Mary McLeod Bethune Council House National Historic Site.

The Commission is composed of 15 members, each of which is appointed by the Secretary for a 4-year term. Nominations are seeking nominations for members representing each of the following categories: three members appointed from recommendations submitted by the National Council of Negro Women, Inc.; two members appointed from recommendations submitted by other national organizations in which Mary McLeod Bethune played a leadership role; two members who shall have professional expertise in the history of African American women; three members who shall have professional expertise in archival management; three members who shall represent the general public; and two members who shall have professional expertise in historic preservation.

Members of the Commission will receive no pay, allowances, or benefits by reason of their service on the Commission. However, while away from their homes or regular places of business in the performance of services for the Commission as approved by the Designated Federal Officer, members will be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in Government service are allowed such expenses under 5 U.S.C. 5703.

Individuals who are federally registered lobbyists are ineligible to serve on FACA and non-FACA boards, committees, or councils in an individual capacity. The term ''individual capacity'' refers to individuals who are appointed to exercise their own individual best judgment on behalf of the government, such as when they are designated Special Government Employees, rather than being appointed to represent a particular interest.

Seeking Nominations For Membership

We are seeking nominations for commission members in all categories. Nominations should include a resume providing an adequate description of the nominee's qualifications, including information that would enable the Department of the Interior to make an informed decision regarding meeting the membership requirements of the Commission and permit the Department to contact a potential member.

Individuals who have already applied for nomination need not reapply unless you would like to update your nomination and/or supporting documentation.

Dated: May 19, 2015.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2015–13116 Filed 5–29–15; 8:45 am]

BILLING CODE 4310–EE–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1070B (Second Review)]

Certain Tissue Paper Products From China; Institution of a Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it has instituted a review pursuant to the Tariff Act of 1930 (''the Act''), as amended, to determine whether revocation of the antidumping duty order on certain tissue paper products (''tissue paper'') from China would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission; [1] to be assured of consideration, the deadline for responses is July 1, 2015. Comments on the adequacy of responses may be filed with the Commission by August 13, 2015.

DATES: *Effective Date:* June 1, 2015.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the

[1] No response to this request for information is required if a currently valid Office of Management and Budget (OMB) number is not displayed; the OMB number is 3117–0016/USITC No. 15–5–337, expiration date June 30, 2017. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436.

Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.— On March 30, 2005, the Department of Commerce issued an antidumping duty order on imports of certain tissue paper products from China (70 FR 16223). Following the five-year reviews by Commerce and the Commission, effective July 20, 2010, Commerce issued a continuation of the antidumping duty order on imports of certain tissue paper products from China (75 FR 42067). The Commission is now conducting a second review pursuant to section 751(c) of the Act, as amended (19 U.S.C. 1675(c)), to determine whether revocation of the order would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. Provisions concerning the conduct of this proceeding may be found in the Commission's Rules of Practice and Procedure at 19 CFR parts 201, Subparts A and B and 19 CFR part 207, Subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct a full review or an expedited review. The Commission's determination in any expedited review will be based on the facts available, which may include information provided in response to this notice.

Definitions.—The following definitions apply to this review:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year review, as defined by the Department of Commerce.

(2) The *Subject Country* in this review is China.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise.* In its original determination and its expedited first five-year review determination, the Commission defined the *Domestic Like Product* as all tissue paper, co-extensive with Commerce's scope. Certain Commissioners defined the *Domestic Like Product* differently in the original determination and the expedited first five-year review determination.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original determination and its expedited first five-year review determination, the Commission defined the *Domestic Industry* as all domestic producers (whether integrated or converters) of tissue paper. Certain Commissioners defined the *Domestic Industry* differently in the original determination and the expedited first five-year review determination.

(5) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

Participation in the proceeding and public service list.—Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission's designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Carol McCue Verratti, Deputy Agency Ethics Official, at 202–205–3088.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will be deemed to consent, unless otherwise specified, for the Commission, its employees, and contract personnel to use the information provided in any other reviews or investigations of the same or comparable products which the Commission conducts under Title VII of the Act, or in internal audits and investigations relating to the programs and operations of the Commission pursuant to 5 U.S.C. Appendix 3.

Written submissions.—Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is July 1, 2015. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct an expedited or full review. The deadline for filing such comments is August 13, 2015. All written submissions must conform with the provisions of sections 201.8 and 207.3 of the Commission's rules and any submissions that contain BPI must also conform with the requirements of sections 201.6 and 207.7 of the Commission's rules. Please be aware that the Commission's rules with respect to filing have changed. The most recent amendments took effect on July 25, 2014. *See* 79 FR 35920 (June 25, 2014), and the revised Commission Handbook on E-filing, available from the

Commission's Web site at *http://edis.usitc.gov.* Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

Inability to provide requested information.—Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to section 776(b) of the Act (19 U.S.C. 1677e(b)) in making its determination in the review.

Information To Be Provided in Response to This Notice of Institution: As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandise,* a foreign producer or exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association, or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping duty order on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry.*

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in the *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries after 2009.

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2014, except as noted (report quantity data in square meters and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Domestic Like Product* (*i.e.,* the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2014 (report quantity data in square meters and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. commercial shipments of *Subject Merchandise* imported from the *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from the *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2014 (report quantity data in square meters and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in the *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in the *Subject Country* (*i.e.,* the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to

operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in the *Subject Country* after 2009, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in the *Subject Country,* and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This proceeding is being conducted under authority of Title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

By order of the Commission.

Issued: May 22, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–12870 Filed 5–29–15; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–473 and 731–TA–1173 (Review)]

Certain Potassium Phosphate Salts From China; Institution of Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it has instituted reviews pursuant to the Tariff Act of 1930 (''the Act''), as amended, to determine whether revocation of the antidumping and countervailing duty orders on certain potassium phosphate salts from China would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission; [1] to be assured of consideration, the deadline for responses is July 1, 2015. Comments on the adequacy of responses may be filed with the Commission by August 13, 2015.

DATES: *Effective Date:* June 1, 2015.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On July 22, 2010, the Department of Commerce issued antidumping and countervailing duty orders on imports of certain potassium phosphate salts from China (75 FR 42682–42684). The Commission is conducting reviews pursuant to section 751(c) of the Act, as amended (19 U.S.C. 1675(c)), to determine whether revocation of the orders would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. Provisions concerning the conduct of this proceeding may be found in the Commission's Rules of Practice and Procedure at 19 CFR parts 201, Subparts A and B and 19 CFR part 207, subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct full or expedited reviews. The Commission's determinations in any expedited reviews will be based on the facts available, which may include information provided in response to this notice.

Definitions.—The following definitions apply to these reviews:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year reviews, as defined by the Department of Commerce.

(2) The *Subject Country* in these reviews is China.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise.* In its original determinations, the Commission defined three separate *Domestic Like Products* comprised of the following potassium phosphate salts, in all grades (*e.g.,* food grade or technical grade) and all forms (*e.g.,* crushed, granule, powder, and fines), and whether anhydrous or in solution: (1) Anhydrous Monopotassium Phosphate (''MKP'') (KH_2PO_4) (also known as Potassium dihydrogen phosphate, KDP, or Monobasic potassium phosphate; (2) anhydrous Dipotassium Phosphate (''DKP'') (K_2HPO_4) (also known as Dipotassium salt, Dipotassium hydrogen orthophosphate, or Potassium phosphate, dibasic; and (3) Tetrapotassium Pyrophosphate (''TKPP'') ($K_4P_2O_7$) (also known as normal potassium pyrophosphate, Diphosphoric acid, or Tetrapotassium salt).

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original determinations, the Commission defined three *Domestic Industries* as follows: (1) All domestic

[1] No response to this request for information is required if a currently valid Office of Management and Budget (OMB) number is not displayed; the OMB number is 3117–0016/USITC No. 15–5–335, expiration date June 30, 2017. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436.

producers of MKP; (2) all domestic producers of DKP; and (3) all domestic producers of TKPP.

(5) The *Order Date* is the date that the antidumping and countervailing duty orders under review became effective. In these reviews, the *Order Date* is July 22, 2010.

(6) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

Participation in the proceeding and public service list.—Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission's designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Carol McCue Verratti, Deputy Agency Ethics Official, at 202–205–3088.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will be deemed to consent, unless otherwise specified, for the Commission, its employees, and contract personnel to use the information provided in any other reviews or investigations of the same or comparable products which the Commission conducts under Title VII of the Act, or in internal audits and investigations relating to the programs and operations of the Commission pursuant to 5 U.S.C. Appendix 3.

Written submissions.—Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is July 1, 2015. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct expedited or full reviews. The deadline for filing such comments is August 13, 2015. All written submissions must conform with the provisions of sections 201.8 and 207.3 of the Commission's rules and any submissions that contain BPI must also conform with the requirements of sections 201.6 and 207.7 of the Commission's rules. Please be aware that the Commission's rules with respect to filing have changed. The most recent amendments took effect on July 25, 2014. *See* 79 FR 35920 (June 25, 2014), and the revised Commission Handbook on E-filing, available from the Commission's Web site at *http://edis.usitc.gov.* Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

Inability to provide requested information.—Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to section 776(b) of the Act (19 U.S.C. 1677e(b)) in making its determinations in the reviews.

Information To Be Provided in Response to This Notice of Institution: Please provide the requested information separately for each *Domestic Like Product,* as defined by the Commission in its original determinations, and for each of the products identified by Commerce as *Subject Merchandise.* As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandise,* a foreign producer or exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association, or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping and countervailing duty orders on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the

Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry.*

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in the *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries since the *Order Date.*

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2014, except as noted (report quantity data in pounds dry weight and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Domestic Like Product* (*i.e.,* the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2014 (report quantity data in pounds dry weight and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of *Subject Merchandise* imported from the *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from the *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2014 (report quantity data in pounds dry weight and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping or countervailing duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in the *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in the *Subject Country* (*i.e.,* the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in the *Subject Country* since the *Order Date,* and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in the *Subject Country,* and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This proceeding is being conducted under authority of Title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

By order of the Commission.

Issued: May 22, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–12876 Filed 5–29–15; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–465 and 731–TA–1161 (Review)]

Certain Steel Grating From China; Institution of Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it has instituted reviews pursuant to the Tariff Act of 1930 (''the Act''), as amended, to determine whether revocation of the antidumping and countervailing duty orders on certain steel grating from China would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission; [1] to be assured of consideration, the deadline for responses is July 1, 2015. Comments on the adequacy of responses may be filed with the Commission by August 13, 2015.

DATES: *Effective Date:* June 1, 2015.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On July 23, 2010, the Department of Commerce issued antidumping and countervailing duty orders on imports of certain steel grating from China (75 FR 43143–43145), as corrected on November 15, 2010 (75 FR 69626). The Commission is conducting reviews pursuant to section 751(c) of the Act, as amended (19 U.S.C. 1675(c)) to determine whether revocation of the orders would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. Provisions concerning the conduct of this proceeding may be found in the Commission's Rules of Practice and Procedure at 19 CFR parts 201, Subparts A and B and 19 CFR part 207, subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct full or expedited reviews. The Commission's determinations in any expedited reviews will be based on the facts available, which may include information provided in response to this notice.

Definitions.—The following definitions apply to these reviews:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year reviews, as defined by the Department of Commerce.

(2) The *Subject Country* in these reviews is China.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise.* In its original determinations, the Commission defined a single *Domestic Like Product* as certain steel grating, coextensive with Commerce's scope.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product*, or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original determination, the Commission defined a single *Domestic Industry* as all producers of certain steel grating. Certain Commissioners defined the *Domestic Industry* differently based on their analysis of related party issues.

(5) The *Order Date* is the date that the antidumping and countervailing duty orders under review became effective. In these reviews, the *Order Date* is July 23, 2010.

(6) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

Participation in the proceeding and public service list.—Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission's designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Carol McCue Verratti, Deputy Agency Ethics Official, at 202–205–3088.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to section 207.3 of the Commission's rules, any

[1] No response to this request for information is required if a currently valid Office of Management and Budget (OMB) number is not displayed; the OMB number is 3117–0016/USITC No. 15–5–336, expiration date June 30, 2017. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436.

person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will be deemed to consent, unless otherwise specified, for the Commission, its employees, and contract personnel to use the information provided in any other reviews or investigations of the same or comparable products which the Commission conducts under Title VII of the Act, or in internal audits and investigations relating to the programs and operations of the Commission pursuant to 5 U.S.C. Appendix 3.

Written submissions.—Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is July 1, 2015. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct expedited or full reviews. The deadline for filing such comments is August 13, 2015. All written submissions must conform with the provisions of sections 201.8 and 207.3 of the Commission's rules and any submissions that contain BPI must also conform with the requirements of sections 201.6 and 207.7 of the Commission's rules. Please be aware that the Commission's rules with respect to filing have changed. The most recent amendments took effect on July 25, 2014. *See* 79 FR 35920 (June 25, 2014), and the revised Commission Handbook on E-filing, available from the Commission's Web site at *http://edis.usitc.gov.* Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

Inability to provide requested information.—Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to section 776(b) of the Act (19 U.S.C. 1677e(b)) in making its determinations in the reviews.

Information To Be Provided In Response to This Notice of Institution: As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is a U.S. producer of the *Domestic Like Product*, a U.S. union or worker group, a U.S. importer of the *Subject Merchandise*, a foreign producer or exporter of the *Subject Merchandise*, a U.S. or foreign trade or business association, or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping and countervailing duty order on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry.*

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in the *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries since the *Order Date.*

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2014, except as noted (report quantity data in kilograms and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Domestic Like Product* (*i.e.*, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from the *Subject Country*, provide the following information on your firm's(s') operations on that product during calendar year 2014 (report quantity data in kilograms and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of *Subject Merchandise* imported from the *Subject Country*; and

(c) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from the *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in the *Subject Country*, provide the following information on your firm's(s') operations on that product during calendar year 2014 (report quantity data in kilograms and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping or countervailing duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in the *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in the *Subject Country* (*i.e.*, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in the *Subject Country* since the *Order Date*, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in the *Subject Country*, and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry*; if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This proceeding is being conducted under authority of Title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

By order of the Commission.

Issued: May 22, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–12872 Filed 5–29–15; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Safe Drinking Water Act

On May 21, 2015, the Department of Justice lodged a proposed consent decree with the United States District Court for the Southern District of New York in the lawsuit entitled *United States* v. *County of Westchester, New York,* Civil Action No. 13 Civ. 5475 (NSR).

The United States filed this lawsuit under the Safe Drinking Water Act (the ''Act''). The complaint alleges that the County of Westchester, New York (the ''Defendant'') violated the Act by failing to ensure that Westchester County Water District No. 1 (''Water District No. 1'') was in compliance with the Long Term 2 Enhanced Surface Water Treatment Rule (the ''Enhanced Water Treatment Rule''), a regulation promulgated pursuant to the Act. The Enhanced Water Treatment Rule required certain public water systems, including Water District No. 1, to implement measures by April 1, 2012 to treat water to prevent *Cryptosporidium* contamination.

The proposed consent decree requires Defendant to perform injunctive relief to bring Water District No. 1 into compliance with the Enhanced Water Treatment Rule. While the injunctive relief is being completed, the proposed consent decree requires Defendant to perform interim measures to provide water that is in compliance with the Enhanced Water Treatment Rule to portions of Water District No. 1 for portions of each year. In addition, the proposed consent decree requires Defendant to pay a civil penalty of $1,108,771, and to perform three supplemental environmental projects (''SEPs'') for the benefit of the residents of Water District No. 1. The SEPs, which have a combined value of $691,229, require Defendant to: (i) Increase the number of days during which the unused pharmaceuticals of residents of Water District No. 1 will be accepted at Defendant's Household Materials Recovery Facility or at other designated sites; (ii) increase the number of days during which the unused hazardous household chemicals of residents of Water District No. 1 will be accepted at Defendant's Household Materials Recovery Facility or at other designated sites; and (iii) purchase at least $100,000 worth of 55-gallon rain barrels for residential collection and storage of roof rainwater runoff, to be distributed to residents of Water District No. 1. The Consent Decree resolves the claims of the United States for the violations alleged in the complaint through the date of lodging of the proposed consent decree.

The publication of this notice opens a period for public comment on the proposed consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *County of Westchester, New York,* 13 Civ. 5475 (NSR), D.J. Ref. No. 90–5–1–1–10536. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*

To submit comments:	*Send them to:*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the proposed consent decree may be examined and downloaded at this Justice Department Web site: *http://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the proposed consent decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $12.25 (25 cents per page reproduction cost) payable to the United States Treasury.

Maureen Katz,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2015–13098 Filed 5–29–15; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; OMB Approvals; H–2B Temporary Employment Certification Program

ACTION: Notice of OMB approval of information collection requirements.

SUMMARY: This notice announces that the Office of Management and Budget has approved the information collections under the Paperwork Reduction Act. The information collections are in effect.

DATES: On April 29, 2015, the Office of Management and Budget (OMB) approved the Department of Labor's emergency information collection requests under the PRA for requirements in 20 CFR part 655, subpart A, as published in the **Federal Register** on April 29, 2015 at 80 FR 24042 and 80 FR 24146. The information collections in the interim final rule *Temporary Non-Agricultural Employment of H–2B Aliens in the United States* were approved under OMB control number 1205–0509, which contains the forms ETA–9142B, *H–2B Application for Temporary Employment Certification, Appendix B, Seafood Industry Attestation;* and ETA–9155, *H–2B Registration.* The current expiration date for OMB authorization for this information collection is October 31, 2015.

The new information collection in the final rule *Wage Methodology for the Temporary Non-Agricultural Employment H–2B Program* was approved under OMB control number 1205–0516, which contains Form ETA–9165, *Employer-Provided Survey Attestations to Accompany H–2B Prevailing Wage Determination Request Based on a Non-OES Survey.* The current expiration date for OMB authorization for this information collection is October 31, 2015.

ADDRESSES: Written comments regarding the burden-hour estimates or other aspects of the information collection requirements contained in 20 CFR part 655, subpart A may be submitted to: William W. Thompson, II, Acting Administrator, Office of Foreign Labor Certification, Room C–4312, 200 Constitution Avenue NW., Washington DC 20210.

FOR FURTHER INFORMATION CONTACT: Brian Pasternak, National Director of Temporary Programs, Office of Foreign Labor Certification, Room C–4312, Employment & Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. Telephone number: 202–693–3010 (this is not a toll-free number). Individuals with hearing or speech impairments may access the telephone number above via TTY by calling the toll-free Federal Information Relay Service at 1–877–889–5627 (TTY/TDD).

SUPPLEMENTARY INFORMATION: OMB has approved the information collection requirements under the PRA contained in two recently revised final regulations in the H–2B Temporary Non-Agricultural Employment Programs published by the Department of Labor in the **Federal Register** on April 29, 2015 at 80 FR 24042 and 80 FR 24146. The preamble to the new regulations stated an effective date of April 29, 2015; however, the regulations were published without specific information about the exact expiration dates or the new control number for the ETA–9165. An agency may not conduct an information collection unless it has a currently valid OMB approval. 44 U.S.C. 3506(c)(1)(B)(iii)(V). OMB issued a formal Notice of Approval on April 29, 2015 after the rules had already been placed on the **Federal Register**'s Electronic Public Inspection Desk and could not be edited to include the OMB control number and exact expiration dates. This is a notice to the public to inform it of the approval of the forms and information collections on the effective date of the rules and to provide the OMB control numbers and expiration dates. The expiration date for OMB authorization for both OMB control numbers 1205–0509 and 1205–0516 and the information collections found therein is October 31, 2015. Because the information collections were approved under PRA emergency procedures codified in 5 CFR 1320.13, the Department will be publishing Notices in the **Federal Register** that invite public comment on the collection requirements as required under 5 CFR 1320.8 in anticipation of extending the information collection requests.

The approved information collections are summarized as follows:

Title of Collection: H–2B Foreign Labor Certification Program.

Forms: H–2B Application for Temporary Employment Certification (ETA–9142B), *Appendix B, Seafood Attestation;* and *H–2B Registration (*ETA–9155).

OMB Control Number: 1205–0509.

Affected Public: Individuals or Households, Private Sector—businesses or other for-profits, Government, State, Local and Tribal Governments.

Estimated Number of Respondents: 7,355.

Frequency: On occasion.

Total Estimated Annual Responses: 184,442.

Estimated Average Time per Response: Various (ten minutes to two hours).

Estimated Total Annual Burden Hours: 47,992 hours.

Total Estimated Annual Other Cost Burden: $351,800.

Title of Collection: Employer-Provided Survey Attestations to Accompany H–2B Prevailing Wage Determination Request Based on a Non-OES Survey.

Form: Employer-Provided Survey Attestations to Accompany H–2B Prevailing Wage Determination Request Based on a Non-OES Survey (ETA–9165).

OMB Control Number: 1205–0516.

Affected Public: Individuals or Households, Private Sector—businesses or other for-profits, Government, State, Local, and Tribal Governments.

Estimated Number of Respondents: 556.

Frequency: On occasion.

Total Estimated Annual Responses: 256.

Estimated Average Time per Response: 1.25 hours.

Estimated Total Annual Burden Hours: 348 hours.

Total Estimated Annual Other Cost Burden: $211,884.

Portia Wu,

Assistant Secretary, Employment and Training Administration.

[FR Doc. 2015–13066 Filed 5–29–15; 8:45 am]

BILLING CODE 4510–FP–P

NUCLEAR REGULATORY COMMISSION

[NRC–2014–0265]

Service Contracts Inventory

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is providing for public information its Inventory of Contracts for Services for Fiscal Year (FY) 2014. The inventory includes service contract actions over $25,000 that were awarded in FY 2014.

DATES: June 1, 2015.

ADDRESSES: Please refer to Docket ID NRC–2014–0265 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2014–0265. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it available in ADAMS) is provided the first time that a document is referenced. The Inventory of Contracts for Services for FY 2014 can be accessed in ADAMS under Accession No. ML14353A174. The inventory was published on the NRC's Web site at the following location: *http://www.nrc.gov/about-nrc/contracting.html.*
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Lori Konovitz, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–0039 or email: *Lori.Konovitz@nrc.gov.*

SUPPLEMENTARY INFORMATION: In accordance with Section 743 of Division C of the FY 2010 Consolidated Appropriations Act, Public Law 111–117, the NRC is publishing this notice to advise the public of the availability of its FY 2014 Service Contracts Inventory. The inventory provides information on service contract actions over $25,000 that were awarded in FY 2014. The information is organized by function to show how contracted resources are distributed throughout the agency. The inventory contains the following data:

1. A description of the services purchased;
2. The total dollar amount obligated for the services under the contract, and the funding source for the contract;
3. The contract type and date of the award;
4. The name of the contractor and place of performance;
5. Whether the contract is a personal services contract; and
6. Whether the contract was awarded on a non-competitive basis.

The NRC will analyze the data in the inventory for the purpose of determining if its contract labor is being used in an effective and appropriate manner and if the mix of federal employees and contractors in the agency is effectively balanced. The inventory does not include contractor proprietary or sensitive information.

Dated at Rockville, Maryland, this 21st day of May 2015.

For the Nuclear Regulatory Commission.

James C. Corbett,

Director, Acquisition Management Division, Office of Administration.

[FR Doc. 2015–13126 Filed 5–29–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0001]

Sunshine Act Meeting Notice

DATE: June 1, 8, 15, 22, 29, July 6, 2015.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed

Week of June 1, 2015

There are no meetings scheduled for the week of June 1, 2015.

Week of June 8, 2015—Tentative

Tuesday, June 9, 2015

9:30 a.m. Briefing on NRC Insider Threat Program (Closed—Ex. 1 & 2).

Thursday, June 11, 2015

10:00 a.m. Meeting with the Advisory Committee on Reactor Safeguards (Public Meeting) (Contact: Edwin Hackett, 301–415–7360).

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of June 15, 2015—Tentative

There are no meetings scheduled for the week of June 15, 2015.

Week of June 22, 2015—Tentative

Tuesday, June 23

9:00 a.m. Briefing on Human Capital and Equal Employment Opportunity (Public Meeting) (Contact: Dafna Silberfeld, 301–287–0737).

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Thursday, June 25, 2015

9:00 a.m. Briefing on Proposed Revisions to Part 10 CFR part 61 and Low-Level Radioactive Waste Disposal (Public Meeting) (Contact: Gregory Suber, 301–415–8087).

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of June 29, 2015—Tentative

There are no meetings scheduled for the week of June 29, 2015.

Week of July 6, 2015—Tentative

Tuesday, July 7, 2015

9:00 a.m. Briefing on Inspections, Tests, Analyses, and Acceptance Criteria (Public Meeting) (Contact: James Beardsley, 301–415–5998).

This meeting will be webcast live at the Web address—*http://www.nrc.gov/*

Thursday, July 9, 2015

9:00 a.m. Briefing on the Mitigation of Beyond Design Basis Events Rulemaking (Public Meeting) (Contact: Tara Inverso, 301–415–1024).

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

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The schedule for Commission meetings is subject to change on short

notice. For more information or to verify the status of meetings, contact Glenn Ellmers at 301–415–0442 or via email at *Glenn.Ellmers@nrc.gov.*

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The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

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The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.* braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301–287–0727, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or email *Brenda.Akstulewicz@nrc.gov* or *Patricia.Jimenez@nrc.gov.*

Dated: May 27, 2015.

Glenn Ellmers,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2015–13156 Filed 5–28–15; 11:15 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–275, 50–323; ASLBP No. 15–941–05–LA–BD01]

Establishment of Atomic Safety and Licensing Board; Pacific Gas & Electric Company

Pursuant to delegation by the Commission, *see* 37 FR 28710 (Dec. 29, 1972), and the Commission's regulations, *see e.g.,* 10 CFR 2.104, 2.105, 2.300, 2.309, 2.313, 2.318, and 2.321, notice is hereby given that an Atomic Safety and Licensing Board (Board) is being established to preside over the following proceeding:

Pacific Gas & Electric Company (Diablo Canyon Power Plant, Units 1 and 2)

This proceeding arises from the Commission's May 21, 2015 decision in CLI–15–14, which refers to the Atomic Safety and Licensing Board Panel a limited portion of a hearing request submitted by Friends of the Earth (FoE) ''to determine whether [FoE] has identified an NRC activity [involving the operating licenses held by Pacific Gas & Electric Company (PG&E) for Diablo Canyon Power Plant Units 1 and 2] that requires an opportunity to request an adjudicatory hearing pursuant to section 189a. of the Atomic Energy Act of 1954, as amended (AEA).'' Slip op. at 2; *see also id.* at 7 (''The scope of the referral is limited to whether the NRC granted PG&E greater authority than that provided by its existing licenses or otherwise altered the terms of PG&E's existing licenses, thereby entitling [FoE] to an opportunity to request a hearing pursuant to AEA section 189a.''). The Commission's referral ''includes such threshold issues as standing, timeliness, and satisfaction of admissibility standards'' (*id.* at 8), and the Commission directed the Board ''to rule on whether [FoE's] hearing request should be granted within 140 days of the date of this decision.'' *Id.* at 8–9.

The Board is comprised of the following administrative judges:

Paul S. Ryerson, Chairman, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Dr. Gary S. Arnold, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Nicholas G. Trikouros, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

All correspondence, documents, and other materials shall be filed in accordance with the NRC E-Filing rule. *See* 10 CFR 2.302.

Dated: May 21, 2015.

E. Roy Hawkens,

Chief Administrative Judge, Atomic Safety and Licensing Board Panel.

[FR Doc. 2015–12933 Filed 5–29–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–391; NRC–2015–0127]

Tennessee Valley Authority; Watts Bar Nuclear Plant, Unit 1

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment request; opportunity to comment, request a hearing, and petition for leave to intervene; order.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an amendment to Facility Operating License No. NPF–90, issued to the Tennessee Valley Authority (TVA), for operation of the Watts Bar Nuclear Plant (WBN), Unit 1. The amendment request would revise the approved Cyber Security Plan for the WBN site, and clarify the demarcation point (so called Bright-Line) between digital components under NRC jurisdiction, and those under the jurisdiction of the Federal Energy Regulatory Commission (FERC). Specifically, certain equipment located within the WBN, but owned by the Transmission and Power Supply business unit, will be classified either as NRC-regulated or FERC-regulated. This demarcation will allow both the NRC and licensee to use the correct process for information associated with the specific equipment. For this amendment request, the NRC proposes to determine that it involves no significant hazards consideration. In addition, the amendment request contains sensitive unclassified non-safeguards information (SUNSI).

DATES: Submit comments by July 1, 2015. Requests for a hearing or petition for leave to intervene must be filed by July 31, 2015. Any potential party as defined in § 2.4 of Title 10 of the *Code of Federal Regulations* (10 CFR), who believes access to SUNSI is necessary to respond to this notice must request document access by June 11, 2015.

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

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0127. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

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

FOR FURTHER INFORMATION CONTACT: Anthony Minarik, Office of Nuclear Reactor Regulation, U.S. Nuclear

Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–6185; email: *Anthony.Minarik@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2015–0127 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0127.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The April 1, 2015, cover letter for TVA's amendment request regarding the revisions to the Cyber Security Plan for the WBN site is available in ADAMS under Accession No. ML15096A151. The enclosures to this letter are security-related and withheld from the public. On May 7, 2015, the licensee provided a supplementary letter that included the discussion of the Significant Hazards Consideration. This letter is publicly available in ADAMS under Accession No. ML15127A511.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2015–0127 in your comment submission.

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

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

II. Introduction

The NRC is considering issuance of an amendment to Facility Operating License No. NPF–90, issued to TVA, for operation of the WBN, Unit 1, located in Rhea County, Tennessee.

The proposed amendment would revise the approved Cyber Security Plan for the WBN site, and clarify the demarcation point (so called Bright-Line) between digital components under NRC jurisdiction, and those under the jurisdiction of FERC.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations.

The Commission has made a proposed determination that the license amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change revises WBN's Cyber Security Plan by clarifying the ''Bright-Line'' demarcation point. This change does not alter accident analysis assumptions, add any initiators, or affect the function of plant systems or the manner in which systems are operated, maintained, modified, tested, or inspected. The proposed change is to clarify the demarcation point; that in itself does not require any plant modifications which affect the performance capability of the structure, systems, and components relied upon to mitigate the consequences of postulated accidents and has no impact on the probability or consequences of an accident previously evaluated.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change revises the WBN Cyber Security Plan to clarify the ''Bright-Line'' demarcation point. This proposed change does not alter accident analysis assumptions, add any initiators, or affect the function of plant systems or the manner in which systems are operated, maintained, modified, tested, or inspected. The proposed change does not require any plant modifications which affect the performance capability of the structures, systems, and components relied upon to mitigate the consequences of postulated accidents. This change also does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

Plant safety margins are established through limiting conditions for operation, limiting safety system settings, and safety limits specified in the technical specifications. The proposed change is to clarify the ''Bright-Line'' demarcation point in the WBN Cyber Security Plan. Because there is no change to these established safety margins, the proposed change does not involve a significant reduction in a margin of safety.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the license amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day notice period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day

comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

III. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this **Federal Register** notice, any person whose interest may be affected by this proceeding and who desires to participate as a party in the proceeding must file a written request for hearing or a petition for leave to intervene specifying the contentions which the person seeks to have litigated in the hearing with respect to the license amendment request. Requests for hearing and petitions for leave to intervene shall be filed in accordance with the NRC's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.*

As required by 10 CFR 2.309, a request for hearing or petition for leave to intervene must set forth with particularity the interest of the petitioner in the proceeding and how that interest may be affected by the results of the proceeding. The hearing request or petition must specifically explain the reasons why intervention should be permitted, with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The hearing request or petition must also include the specific contentions that the requestor/petitioner seeks to have litigated at the proceeding.

For each contention, the requestor/petitioner must provide a specific statement of the issue of law or fact to be raised or controverted, as well as a brief explanation of the basis for the contention. Additionally, the requestor/petitioner must demonstrate that the issue raised by each contention is within the scope of the proceeding and is material to the findings that the NRC must make to support the granting of a license amendment in response to the application. The hearing request or petition must also include a concise statement of the alleged facts or expert opinion that support the contention and on which the requestor/petitioner intends to rely at the hearing, together with references to those specific sources and documents. The hearing request or petition must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact, including references to specific portions of the application for amendment that the petitioner disputes and the supporting reasons for each dispute. If the requestor/petitioner believes that the application for amendment fails to contain information on a relevant matter as required by law, the requestor/petitioner must identify each failure and the supporting reasons for the requestor's/petitioner's belief. Each contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who does not satisfy these requirements for at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that person's admitted contentions, including the opportunity to present evidence and to submit a cross-examination plan for cross-examination of witnesses, consistent with NRC regulations, policies, and procedures. The presiding officer will set the time and place for any prehearing conferences and evidentiary hearings, and the appropriate notices will be provided.

Hearing requests or petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i)–(iii).

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of any amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

IV. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will

establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's ''Guidance for Electronic Submission,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as Social Security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, in some instances, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

For further details with respect to this action, see the application for license amendment dated April 1, 2015, as supplemented by the letter dated May 7, 2015.

Attorney for licensee: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, ET 11A, Knoxville, Tennessee 37902.

NRC Branch Chief: Jessie F. Quichocho.

Tennessee Valley Authority, Docket No. 50–390, Watts Bar Nuclear Plant, Unit 1, Rhea County, Tennessee

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing SUNSI.

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI is necessary to respond to this notice may request such access. A ''potential party'' is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication of this notice will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requester shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Associate General Counsel for Hearings, Enforcement and Administration, Office of the General Counsel, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email address for the Office of the Secretary and the Office of the General Counsel are

Hearing.Docket@nrc.gov and *OGCmailcenter@nrc.gov,* respectively.[1] The request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1); and

(3) The identity of the individual or entity requesting access to SUNSI and the requester's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly-available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C.(3) the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order [2] setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after the requestor is granted access to that information. However, if more than 25 days remain between the date the petitioner is granted access to the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline. This provision does not extend the time for filing a request for a hearing and petition to intervene, which must comply with the requirements of 10 CFR 2.309.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff after a determination on standing and need for access, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) The requester may challenge the NRC staff's adverse determination by filing a challenge within five days of receipt of that determination with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an administrative law judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) officer if that officer has been designated to rule on information access issues.

H. Review of Grants of Access. A party other than the requester may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed with the Chief Administrative Judge within five days of the notification by the NRC staff of its grant of access.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.[3]

I. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. Attachment 1 to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

It is so ordered.

Dated at Rockville, Maryland, this 26th day of May, 2015.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING

0	Publication of **Federal Register** notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) with information: Supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60	Deadline for submitting petition for intervention containing: (i) Demonstration of standing; and (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).
20	U.S. Nuclear Regulatory Commission (NRC) staff informs the requester of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).

[1] While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's ''E-Filing Rule,'' the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

[2] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

[3] Requesters should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING—Continued

25	If NRC staff finds no ''need'' or no likelihood of standing, the deadline for petitioner/requester to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds ''need'' for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.
A	If access granted: Issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

[FR Doc. 2015–13163 Filed 5–29–15; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Federal Prevailing Rate Advisory Committee; Cancellation of Upcoming Meeting

AGENCY: U.S. Office of Personnel Management.

ACTION: Notice.

SUMMARY: The Federal Prevailing Rate Advisory Committee is issuing this notice to cancel the July 16, 2015, public meeting scheduled to be held in Room 5A06A, U.S. Office of Personnel Management Building, 1900 E Street NW., Washington, DC. The original **Federal Register** notice announcing this meeting was published Monday, December 8, 2014, at 79 FR 72714, with a correction published Wednesday, December 17, 2014, at 79 FR 75189.

FOR FURTHER INFORMATION CONTACT: Madeline Gonzalez, 202–606–2838, or email *pay-leave-policy@opm.gov.*

U.S. Office of Personnel Management.

Sheldon Friedman,

Chairman, Federal Prevailing Rate Advisory Committee.

[FR Doc. 2015–13153 Filed 5–29–15; 8:45 am]

BILLING CODE 6325–49–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2015–74; Order No. 2502]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning an additional Global Expedited Package Services 3 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* June 2, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

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

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

On May 22, 2015, the Postal Service filed notice that it has entered into an additional Global Expedited Package Services 3 (GEPS 3) negotiated service agreement (Agreement).[1]

To support its Notice, the Postal Service filed a copy of the Agreement, a copy of the Governors' Decision authorizing the product, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket No. CP2015–74 for consideration of matters raised by the Notice.

The Commission invites comments on whether the Postal Service's filing is consistent with 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than June 2, 2015. The public portions of the filing can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Curtis E. Kidd to serve as Public Representative in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2015–74 for consideration of the matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, Curtis E. Kidd is appointed to serve as an officer of the Commission to represent the

[1] Notice of United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 3 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, May 22, 2015 (Notice).

interests of the general public in this proceeding (Public Representative).

3. Comments are due no later than June 2, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2015–13069 Filed 5–29–15; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2015–75; Order No. 2501]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning an additional Global Expedited Package Services 3 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* June 2, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

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

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

On May 22, 2015, the Postal Service filed notice that it has entered into an additional Global Expedited Package Services 3 (GEPS 3) negotiated service agreement (Agreement).[1]

To support its Notice, the Postal Service filed a copy of the Agreement, a copy of the Governors' Decision authorizing the product, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket No. CP2015–75 for consideration of matters raised by the Notice.

The Commission invites comments on whether the Postal Service's filing is consistent with 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than June 2, 2015. The public portions of the filing can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Kenneth R. Moeller to serve as Public Representative in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2015–75 for consideration of the matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, Kenneth R. Moeller is appointed to serve as an officer of the Commission to represent the interests of the general public in this proceeding (Public Representative).

3. Comments are due no later than June 2, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2015–13068 Filed 5–29–15; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2015–77; Order No. 2511]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning an additional Global Expedited Package Services 3 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* June 3, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

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

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

On May 26, 2015, the Postal Service filed notice that it has entered into an additional Global Expedited Package Services 3 (GEPS 3) negotiated service agreement (Agreement).[1]

To support its Notice, the Postal Service filed a copy of the Agreement, a copy of the Governors' Decision authorizing the product, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket No. CP2015–77 for consideration of matters raised by the Notice.

The Commission invites comments on whether the Postal Service's filing is consistent with 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than June 3, 2015. The public portions of the filing can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints James F. Callow to serve as Public Representative in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2015–77 for consideration of the matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, James F. Callow is appointed to serve as an officer of the Commission to represent the interests of the general public in this proceeding (Public Representative).

3. Comments are due no later than June 3, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2015–13120 Filed 5–29–15; 8:45 am]

BILLING CODE 7710–FW–P

[1] Notice of United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 3 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, May 22, 2015 (Notice).

[1] Notice of United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 3 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, May 26, 2015 (Notice).

POSTAL REGULATORY COMMISSION

[Docket No. CP2013–83; Order No. 2503]

Amendment to Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning an amendment to Priority Mail Contract 65 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* June 2, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

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

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

On May 22, 2015, the Postal Service filed notice that it has agreed to an Amendment to the existing Priority Mail Contract 65 negotiated service agreement approved in this docket.[1] In support of its Notice, the Postal Service includes a redacted copy of the Amendment.

The Postal Service also filed the unredacted Amendment. The Postal Service seeks to incorporate by reference the Application for Non-Public Treatment originally filed in this docket for the protection of information that it has filed under seal. *Id.*

The Amendment concerns changes to the Customer's mailing address, the location of Customer's distribution center, and volume commitment under the contract. *Id.,* Attachment A at 1.

The Postal Service intends for the Amendment to become effective one business day after the date that the Commission completes its review of the Notice. Notice at 1. The Postal Service asserts that the Amendment will not materially affect the cost coverage of Priority Mail Contract 65. *Id.*

[1] Notice of United States Postal Service of Amendment to Priority Mail Contract 65, with Portions Filed Under Seal, May 22, 2015 (Notice).

II. Notice of Filings

The Commission invites comments on whether the changes presented in the Postal Service's Notice are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR 3015.5, and 39 CFR part 3020, subpart B. Comments are due no later than June 2, 2015. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Lyudmila Y. Bzhilyanskaya to represent the interests of the general public (Public Representative) in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission reopens Docket No. CP2013–83 for consideration of matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, the Commission appoints Lyudmila Y. Bzhilyanskaya to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

3. Comments are due no later than June 2, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2015–13070 Filed 5–29–15; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2015–76; Order No. 2510]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning an additional Global Expedited Package Services 3 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* June 3, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

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

SUPPLEMENTARY INFORMATION:

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I. Introduction

On May 26, 2015, the Postal Service filed notice that it has entered into an additional Global Expedited Package Services 3 (GEPS 3) negotiated service agreement (Agreement).[1]

To support its Notice, the Postal Service filed a copy of the Agreement, a copy of the Governors' Decision authorizing the product, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket No. CP2015–76 for consideration of matters raised by the Notice.

The Commission invites comments on whether the Postal Service's filing is consistent with 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than June 3, 2015. The public portions of the filing can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Cassie D'Souza to serve as Public Representative in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2015–76 for consideration of the matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, Cassie D'Souza is appointed to serve as an officer of the Commission to represent the interests of the general public in this proceeding (Public Representative).

3. Comments are due no later than June 3, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2015–13110 Filed 5–29–15; 8:45 am]

BILLING CODE 7710–FW–P

[1] Notice of United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 3 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, May 26, 2015 (Notice).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75039; File No. SR–MSRB–2015–02]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Order Granting Approval of a Proposed Rule Change Consisting of Proposed Amendments to the MSRB Rule G–14 RTRS Procedures, and the Real-Time Transaction Reporting System and Subscription Service

May 22, 2015.

I. Introduction

On March 19, 2015, the Municipal Securities Rulemaking Board (the ''MSRB'' or ''Board'') filed with the Securities and Exchange Commission (the ''SEC'' or ''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 consisting of proposed amendments to the MSRB Rule G–14 RTRS procedures, and the Real-Time Transaction Reporting System and subscription service (the ''proposed rule change''). The proposed rule change was published for comment in the **Federal Register** on March 27, 2015.[3]

The Commission received three comment letters on the proposed rule change.[4] On May 20, 2015, the MSRB submitted a response to these comments.[5] This order approves the proposed rule change.

II. Description of the Proposed Rule Change

Rule G–14 on reports of sales or purchases requires brokers, dealers and municipal securities dealers (collectively ''dealers'') to report all executed transactions in municipal securities to the MSRB's Real-Time Transaction Reporting System (''RTRS'') within 15 minutes of the time of trade, with limited exceptions.[6] The MSRB makes certain transaction data reported to RTRS available to the general public through the Electronic Municipal Market Access (''EMMA'') Web site at no cost, and disseminates such data through paid subscription services to market data vendors, institutional market participants and others that subscribe to the data feed.[7] The MSRB believes that RTRS serves the dual objectives of price transparency and market surveillance.[8] According to the MSRB, the proposed rule change would enhance the post-trade price transparency information provided through RTRS.[9] A full description of the proposed rule change is contained in the Proposing Release.

1. Expanding the Application of Existing List Offering Price and Takedown Transaction Indicator

The MSRB stated that the proposed rule change would expand the application of the List Offering Price and Takedown Transaction indicators to sale transactions by distribution participant dealers to customers at the list offering price and sale transactions by a sole underwriter or syndicate manager to distribution participant dealers.[10] The MSRB stated that since the introduction of the List Offering Price indicator in 2005 and Takedown Transaction indicator in 2007, certain market practices in this area have evolved and the proposed rule change would expand the application of the indicators to require reporting of such market practices to RTRS.[11]

2. Eliminating the Requirement for Dealers To Report Yield on Customer Trade Reports

The MSRB stated that the proposed rule change would eliminate the requirement for dealers to include yield on customer trade reports.[12] The MSRB represented that it would calculate and disseminate yield on customer trade reports, consistent with the manner in which it calculates and includes in disseminated RTRS information yield on inter-dealer trades.[13] The MSRB believes that this would remove one aspect of a dealer's burden in reporting customer transactions to the MSRB in compliance with MSRB Rule G–14 and ensure that the calculation and dissemination of yields for both inter-dealer and customer transactions are consistent.[14]

3. Establishing a New Indicator for Customer Trades Involving Non-Transaction-Based Compensation Arrangements

The MSRB stated that the proposed rule change would require dealers to include a new indicator on their trade reports that would be disseminated publicly to distinguish customer transactions that do not include a dealer compensation component and those that include a mark-up, mark-down, or a commission.[15] The MSRB believes the proposed rule change would improve the usefulness of the transaction information disseminated publicly.[16]

4. Establishing a New Indicator for ATS Transactions

The MSRB stated that the proposed rule change would establish an additional new indicator to better ascertain the extent to which alternative trading systems (''ATSs'') are used in the municipal market and to indicate to market participants on disseminated transaction information that an ATS was used.[17] The MSRB believes that identifying in disseminated transaction information that an ATS was employed should facilitate higher quality research and analysis of market structure by providing information about the extent to which ATSs are used and should complement the existing indicator disseminated for transactions involving a broker's broker.[18]

5. Effective Date of the Proposed Rule Change/Testing Period

The MSRB proposed that an effective date for the proposed rule change would be announced by the MSRB in a notice published on the MSRB's Web site.[19] The MSRB stated that the date would be no later than May 23, 2016, and announced no later than sixty (60) days prior to the effective date.[20] The MSRB believed that such effective date would provide time for the MSRB to undertake the programming changes to implement the proposed rule change, as well as provide an adequate testing period for dealers and subscribers that interface with RTRS.[21] Also, the MSRB plans to provide a six month testing period in advance of the effective date.[22]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 74564 (March 23, 2015), 80 FR 16466 (March 27, 2015) (the ''Proposing Release'').

[4] *See* Letters from Leslie M. Norwood, Managing Director and Associate General Counsel, Securities Industry and Financial Markets Association (''SIFMA''), dated April 17, 2015 (''SIFMA Letter''); Michael Nicholas, Chief Executive Officer, Bond Dealers of America (''BDA''), dated April 17, 2015 (''BDA Letter''); and David T. Bellaire, Esq., Executive Vice President & General Counsel, Financial Services Institute (''FSI''), dated April 17, 2015 (''FSI Letter'').

[5] *See* Letter from Justin R. Pica, Director of Product Management—Market Transparency, MSRB, dated May 20, 2015 (''MSRB Response Letter'').

[6] *See supra* note 3.

[7] *Id.*

[8] *Id.*

[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *Id.*

[19] *Id.*

[20] *Id.*

[21] *Id.*

[22] *Id.*

III. Summary of Comments Received and the MSRB's Response

As noted previously, the Commission received three comment letters on the proposed rule change.[23] FSI generally supports the proposed rule change.[24] BDA generally supports the proposed rule change but suggested an extension of the testing period.[25] SIFMA expresses concerns and provides suggestions about certain aspects of the proposed rule change.[26] A full description of the comments and response by the MSRB are contained in the comments letters and MSRB Response Letter, respectively.[27]

1. Expanding the Application of Existing List Offering Price and Takedown Transaction Indicator

SIFMA generally supports this aspect of the proposed rule change.[28] However, SIFMA requests that if dealers are currently using the List Offering Price and Takedown Transaction indicator for group net or net designated orders, or for distribution agreement trades, that they be permitted to continue to do so until the proposed rule change is effective, without risk of an enforcement action.[29] The MSRB responded by stating that it does not believe it would be fair to those dealers that have not programmed systems to use the existing List Offering Price and Takedown Transaction indicator in the expanded manner contemplated in the proposed rule change to advance the timing of the effective date of this component of the proposed rule change.[30] Also, the MSRB does not believe such a request is relevant to a determination of whether to approve the proposed rule change.[31]

2. Eliminating the Requirement for Dealers To Report Yield on Customer Trade Reports

SIFMA generally supports this aspect of the proposed rule change.[32] However, SIFMA notes that reporting yield on trade reports alerts dealers to trades where the dealer calculated yield is outside the acceptable tolerance from the MSRB calculated yield.[33] SIFMA notes that such alert mechanism would be eliminated if the proposed rule change is approved.[34] The MSRB responded by noting that while such alert mechanism does provide benefit in identifying security master and day count discrepancies, the MSRB does not believe that this benefit outweighs the burden on dealers associated with researching and reconciling all questionable errors.[35] Also, the MSRB notes that dealers would continue to be able to compare dealer calculated yields with MSRB calculated yields by viewing MSRB calculated yields on the EMMA Web site.[36]

In addition, SIFMA continues to have concerns that the proposed rule change may lead to investor confusion because not all transactions are consummated based on yield to worst.[37] SIFMA believes that there are many reasons and scenarios why the dealer calculated yield and the MSRB's calculations of yield might not match, such as trading based on yield-to-average life for continuously callable securities, and differences in day counts relating to questionable holidays or market closes.[38] The MSRB responded by stating that the MSRB yield calculations under the proposed rule change would be done in a manner consistent with the requirements of MSRB Rule G–15(a) on customer confirmations.[39] Accordingly, the MSRB believes irrespective of the basis on which the transaction was executed, the yield calculation performed by RTRS under the proposed rule change would match the calculation as required to be performed by dealers when generating customer confirmations.[40] Also, the MSRB states that with regard to the potential for differing MSRB and dealer call information resulting in differing MSRB and dealer calculated yields, the MSRB plans to display the call price and date to which yield was calculated, which should provide sufficient transparency to the inputs used in MSRB yield calculations to explain any calculation differences that arise.[41]

3. Establishing a New Indicator for Customer Trades Involving Non-Transaction-Based Compensation Arrangements

SIFMA acknowledges that the establishment of a new indicator to indicate trades with non-transaction-based compensation would be helpful for transparency purposes.[42] However, SIFMA suggest that a more cost efficient alternative would be for the MSRB to disseminate information it already collects: Whether a trade is done as agent or as principal, and whether the MSRB has added commission in to ''normalize'' agency trades.[43] The MSRB responded by stating it believes that to ensure that this new indicator applies to all transactions involving non-transaction-based compensation, it is critical that the indicator apply to principal trades that do not include a mark-up or mark-down.[44] The MSRB also believes that it is important for dealers to affirmatively indicate on agency transactions that no commission was charged using the new indicator.[45] The MSRB believes this would provide for an additional data quality measure as well as enable dealers to program systems to include the indicator for all transactions involving non-transaction-based compensation as opposed to only a subset of such transactions.[46]

In addition, SIFMA suggests modifying the proposed definition of ''non-transaction-based compensation arrangement transaction.'' [47] Specifically, SIFMA requests that the definition be limited to transactions involving non-transaction-based compensation ''in a customer account that is subject to an arrangement that does not provide for dealer compensation to be paid on a transaction-based basis.'' [48] The MSRB responded by stating that it is not proposing to limit the application of the indicator in this manner because this indicator is intended to distinguish in price transparency data all customer transactions that do not include a dealer compensation component from those that include a mark-up, mark-down or commission and is not intended to distinguish such transactions based on the type of compensation arrangement associated with a customer account.[49]

4. Establishing a New Indicator for ATS Transactions

SIFMA suggests an alternative where the MSRB is responsible for flagging ATS trades when an ATS firm takes a principal position between a buyer and a seller, similar to how it currently flags trades between dealers and municipal securities broker's brokers.[50] SIFMA believes this would eliminate the unnecessary and burdensome requirements of the proposed rule

[23] *See supra* notes 4 and 5.
[24] *See* FSI Letter.
[25] *See* BDA Letter.
[26] *See* SIFMA Letter.
[27] *See supra* notes 4 and 5.
[28] *See* SIFMA Letter.
[29] *Id.*
[30] *See* MSRB Response Letter.
[31] *Id.*
[32] *See* SIFMA Letter.
[33] *Id.*
[34] *Id.*
[35] *See* MSRB Response Letter.
[36] *Id.*
[37] *See* SIFMA Letter.
[38] *Id.*
[39] *See* MSRB Response Letter.
[40] *Id.*
[41] *Id.*
[42] *See* SIFMA Letter.
[43] *Id.*
[44] *See* MSRB Response Letter.
[45] *Id.*
[46] *Id.*
[47] *See* SIFMA Letter.
[48] *Id.*
[49] *See* MSRB Response Letter.
[50] *See* SIFMA Letter.

change.[51] The MSRB responded by stating that it believes a consistent approach should be taken for all transactions executed using the services of an ATS by requiring dealers to include the ATS indicator on trade reports, regardless of whether the ATS takes a principal position.[52] Also, the MSRB believes that this approach would reduce the potential for dealer confusion surrounding the requirement to include the ATS indicator and would help ensure that a dealer currently using the services of an ATS that takes a principal position is prepared to include an ATS indicator on trade reports if that ATS determines in the future to change its business practice and not take a principal position between the buyer and seller.[53]

5. Economic Considerations

SIFMA expresses concern about the costs and burdens associated with the proposed rule change.[54] SIFMA believes that evaluating the costs and burdens of new regulation and weighing those costs against any benefits derived from such new regulation, is critical to ensure efficient regulation.[55] SIFMA states that the proposed rule change will drive up transaction costs and certain aspects of the proposed rule change do not measure up to the costs and burdens that will be imposed upon dealers.[56] The MSRB responded by noting that in each of the three solicitations for public comment the MSRB requested input on the operational costs and burdens of each proposed change as well as the benefits that could be achieved.[57] According to the MSRB, the responses from commenters, to the extent they addressed those issues, well informed the MSRB's determination to seek those changes that would balance the improvements to post-trade price transparency with the regulatory burdens that would be imposed on dealers.[58] Also, the comments received through the public comment process enabled the MSRB to refine a broad set of potential changes that could be made to the limited set of changes in the proposed rule change.[59] The MSRB believes that the proposed rule change best balances the improvements to post-trade price transparency that would be gained with the regulatory burdens that would be imposed on dealers.[60]

6. Effective Date of the Proposed Rule Change/Testing Period

SIFMA requests that the MSRB publish technical specifications related to the proposed rule change at least nine months prior to the effective date of the proposed rule change.[61] BDA notes that smaller dealers with fewer IT resources may need more than six months to make changes necessary to comply with the proposal.[62] Specifically, BDA requests a testing period of at least nine months prior to implementation.[63] The MSRB anticipates publishing updated technical specifications in early September 2015.[64] In response to comments from SIFMA and BDA, the MSRB now intends to set a specific effective date of May 23, 2016, which is the latest effective date contemplated by the proposed rule change. The MSRB believes this effective date would likely provide dealers and subscribers with nearly nine months to make necessary system changes after publication by the MSRB of technical specifications.[65]

IV. Discussion and Commission Findings

The Commission has carefully considered the proposed rule change, the comments received, and the MSRB's response to such comments. The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to the MSRB.

In particular, the Commission finds that the proposed rule change is consistent with Section 15B(b)(2)(C) of the Act,[66] which requires, among other things, that the rules of the MSRB be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in municipal securities and municipal financial products, to remove impediments to and perfect the mechanism of a free and open market in municipal securities and municipal financial products, and, in general, to protect investors, municipal entities, obligated persons, and the public interest. The Commission believes that the proposed rule change is consistent with Section 15B(b)(2)(C) of the Act because the proposed rule change is reasonably designed to remove impediments to and perfect the mechanism of a free and open market in municipal securities by increasing the quality and usefulness of the post-trade price transparency information provided through RTRS. As noted by the MSRB, the (i) expansion of the application of the existing List Offering Price and Takedown Transaction indicator to cases involving distribution participant dealers and takedown transactions that are not at a discount from the list offering price, (ii) establishment of a new indicator for customer trades involving non-transaction-based compensation arrangements, and (iii) establishment of a new indicator for ATS transactions would enable users of the post-trade price transparency information provided through RTRS to better understand the pricing of certain transactions as well as how such transactions were executed.[67] As further noted by the MSRB, identifying in disseminated transaction information that an ATS was employed should facilitate higher quality research and analysis of market structure by providing information about the extent to which ATSs are used and should complement the existing indicator disseminated for transactions involving a broker's broker.[68] Accordingly, the Commission believes that the proposed rule change would contribute to the MSRB's continuing efforts to improve market transparency and to protect investors, municipal entities, obligated persons and the public interest.

In approving the proposed rule change, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation.[69] The Commission recognizes that the proposed rule change would impose a burden on dealers and subscribers that interface with RTRS to comply with the reporting and dissemination of the new indicators that would be required by the proposed rule change. However, the Commission believes that the potential burden created by the proposed rule change is likely outweighed by the benefits, such as increasing the quality and usefulness of post-trade price transparency information. Also, the Commission believes that the proposed rule change includes accommodations that help promote efficiency. Specifically, the

[51] *Id.*
[52] *See* MSRB Response Letter.
[53] *Id.*
[54] *See* SIFMA Letter.
[55] *Id.*
[56] *Id.*
[57] *See* MSRB Response Letter.
[58] *Id.*
[59] *Id.*
[60] *Id.*
[61] *See* SIFMA Letter.
[62] *See* BDA Letter.
[63] *Id.*
[64] *See* MSRB Response Letter.
[65] *Id.*
[66] 15 U.S.C. 78*o*–4(b)(2)(C).
[67] *See supra* note 4.
[68] *Id.*
[69] 15 U.S.C. 78c(f).

proposed rule change would eliminate the requirement for dealers to include yield on customer trade reports. The Commission believes that this would remove one aspect of a dealer's burden in reporting customer transactions to the MSRB in compliance with MSRB Rule G–14. Furthermore, the MSRB has revised its implementation schedule in response to comments from BDA and SIFMA, which would likely provide dealers and subscribers with nearly nine months to make necessary system changes after publication by the MSRB of the technical specifications. This accommodation would likely provide dealers and subscribers with sufficient time to make any required changes in due course without causing adverse disruptions. The Commission does not believe that the proposed rule change would impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act because the requirements of the proposed rule change would apply equally to all dealers who report trade information to RTRS.

As noted above, the Commission received three comment letters on the filing. The Commission believes that the MSRB considered carefully and responded adequately to comments and concerns regarding the proposed rule change. Although one commenter suggested changes and opposed certain aspects of the proposed rule change, the Commission notes that no commenters argued that the proposed rule change was inconsistent with the applicable provisions of the Act.

For the reasons noted above, including those discussed in the MSRB Response Letter, the Commission believes that the proposed rule change is consistent with the Act.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[70] that the proposed rule change (SR–MSRB–2015–02) be, and hereby is, approved.

For the Commission, pursuant to delegated authority.[71]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–13082 Filed 5–29–15; 8:45 am]

BILLING CODE 8011–01–P

[70] 15 U.S.C. 78s(b)(2).

[71] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75041; File No. SR–Phlx–2015–45]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Exchange's Pricing Schedule Under Section VIII With Respect to Execution and Routing of Orders in Securities Priced at $1 or More Per Share

May 26, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 18, 2015, 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, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's Pricing Schedule under Section VIII, entitled ''NASDAQ OMX PSX FEES,'' with respect to execution and routing of orders in securities priced at $1 or more per share.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqomxphlx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend certain charges and fees for order execution and routing applicable to the use of the order execution and routing services of the NASDAQ OMX PSX System (''PSX'') by member organizations for all securities traded at $1 or more per share.

Specifically, the charge to a member organization that executes in PSX will increase to $0.0029 per share executed regardless of where the shares are listed. This means an increase from: (i) $0.0026 to $0.0029 per share executed for shares executed in The NASDAQ Stock Market LLC (''Nasdaq'')-listed securities; (ii) $0.0025 to $0.0029 per share executed for shares executed in New York Stock Exchange (''NYSE'')-listed securities; and (iii) $0.0026 to $0.0029 per share executed for shares in securities listed on exchanges other than Nasdaq or NYSE. The Exchange believes that these increases enable it to balance the need to fund credits and operational costs.

The Exchange will also increase certain credits to member organizations that provide liquidity through PSX. Specifically, the credit to a member organization that executes in PSX for a displayed quote/order will increase from $0.0025 to $0.0028 per share executed for quotes/orders entered by a member organization that provides and accesses 0.35% or more of Consolidated Volume during the month—previously this rate required adding 0.12% of Consolidated Volume. The term ''accesses'' is another way of saying taking liquidity. This change also eliminates the requirements that (i) the quote/order is entered through a PSX Market Participant ID (''MPID'') through which the member organization displays, on average over the course of the month, 100 shares or more at the national best bid and/or national best offer at least 25% of the time during regular market hours in the security that is the subject of the quote/order, or (ii) the member organization displays, on average over the course of the month, 100 shares or more at the national best bid and/or national best offer at least 25% of the time during regular market hours in 500 or more securities. The Exchange believes that eliminating these requirements will encourage firms to participate in PSX by allowing their participation in the market to define the credit rate they receive.

The Exchange will also increase the credit to a member organization that

executes in PSX for a displayed quote/order from $0.0024 to $0.0027 per share executed for quotes/orders entered by a member organization that provides and accesses 0.25% or more of Consolidated Volume during the month—previously this rate required adding 0.04% of Consolidated Volume.

The Exchange will similarly increase the credit to a member organization that executes in PSX for a displayed quote/order from $0.0021 to $0.0025 per share executed for quotes/orders entered by a member organization that provides and accesses 0.05% or more of Consolidated Volume during the month—previously this required that the member organization provide an average daily volume of 100,000 or more.

The Exchange is also adding a new tier for displayed quotes/orders of $0.0023 per share executed for quotes/orders entered by a member organization that provides and accesses daily volume of 100,000 or more shares during the month.

The Exchange will also increase the credit to a member organization that executes in PSX for all other displayed quotes/orders from $0.0015 to $0.0020 per share executed.

The Exchange is also adding another new tier for displayed quotes/orders with an order size of 2,000 or more shares that will receive a $0.0001 credit in addition to the credits discussed above. Orders modified by the PSX participant entering the order or by the PSX System processes so that after such modification the unexecuted order size is below 2,000 shares will no longer qualify as an order of 2,000 or more shares.

The Exchange is also adding a new credit tier for non-displayed orders of a $0.0015 per share executed credit for orders with midpoint pegging that provide liquidity entered by a member organization that provides 1,000,000 shares or more average daily volume of non-displayed liquidity during the month.

Finally, the Exchange is clarifying that the credit tier for non-displayed orders of $0.0010 per share executed will continue to apply to all other orders with midpoint pegging that provide liquidity.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[3] in general, and with Section 6(b)(4) and 6(b)(5) of the Act,[4] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which the Exchange operates or controls, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The proposed increases to the credits and charges in the fee schedule under the Exchange's Pricing Schedule under Section VIII are reflective of the Exchange's ongoing efforts to use pricing incentive programs to attract order flow to the Exchange and improve market quality. The goal of these pricing incentives is to provide meaningful incentives for members to increase their participation on the Exchange.

First, the Exchange is proposing modest increases to the charges that a member organization entering an order that executes in PSX from: (i) $0.0026 to $0.0029 per share executed for shares executed in Nasdaq-listed securities; (ii) $0.0025 to $0.0029 per share executed for shares executed in NYSE-listed securities; and (iii) $0.0026 to $0.0029 per share executed for shares in securities listed on exchanges other than Nasdaq or NYSE. The Exchange believes that these modest increases are reasonable because they reflect the Exchange's need to adjust its credits and fees in response to the costs and benefits provided by the Exchange. Additionally, these modest increases are reasonable because the Exchange is able to balance the need to fund credits and operational costs.

The Exchange also believes that the proposed changes are consistent with an equitable allocation of fees and are not unfairly discriminatory because they apply to all member organizations that enter orders that execute in PSX and affects all members equally in the same way.

Next, the Exchange proposes to increase the credit to a member organization that executes in PSX for a displayed quote/order from $0.0025 to $0.0028 per share executed for quotes/orders entered by a member organization that provides and accesses 0.35% or more of Consolidated Volume during the month (previously this rate required adding 0.12% of Consolidated Volume) and eliminate the requirements that (i) the quote/order is entered through a PSX MPID through which the member organization displays, on average over the course of the month, 100 shares or more at the national best bid and/or national best offer at least 25% of the time during regular market hours in the security that is the subject of the quote/order, or (ii) the member organization displays, on average over the course of the month, 100 shares or more at the national best bid and/or national best offer at least 25% of the time during regular market hours in 500 or more securities. The Exchange believes these changes are reasonable because increasing the credit and replacing the qualifying requirements with a single increased ''provides and accesses Consolidated Volume'' requirement provides member organizations with a simpler, less confusing process for determining eligibility for the credit. Additionally, the Exchange believes increasing this pricing incentive will provide meaningful incentives for members to increase their participation on the Exchange. The Exchange believes including ''accesses'' as part of the criteria will increase the quality of the market by allowing firms to decide how to participate most meaningfully on PSX. The requirement to provide and access 0.35% is reasonable because by achieving this activity level firms will be improving the market quality on PSX and thus receive a correspondingly higher credit than those firms that do not participate as actively on PSX. The Exchange also believes that the proposed rule change is consistent with an equitable allocation of fees and is not unfairly discriminatory because it affects all members equally and in the same way.

The Exchange also proposes to increase the credit to a member organization that executes in PSX for a displayed quote/order from $0.0024 to $0.0027 per share executed for quotes/orders entered by a member organization that provides and accesses 0.25% or more of Consolidated Volume during the month—previously this rate required adding 0.04% of Consolidated Volume. The Exchange believes the proposed change is reasonable because increasing this pricing incentive will provide meaningful incentives for members to increase their participation on the Exchange. The Exchange believes including ''accesses'' as part of the criteria will increase the quality of the market by allowing firms to decide how to participate most meaningfully on PSX. The requirement to provide and access 0.25% is reasonable because by achieving this activity level firms will be improving the market quality on PSX and thus receive a correspondingly higher credit than those firms that do not participate as actively on PSX. The Exchange also believes that the proposed rule change is consistent with an equitable allocation of fees and is not unfairly discriminatory because it affects all members equally and in the same way.

[3] 15 U.S.C. 78f.

[4] 15 U.S.C. 78f(b)(4) and (5).

Additionally, the Exchange proposes to increase the credit to a member organization that executes in PSX for a displayed quote/order from $0.0021 to $0.0025 per share executed for quotes/orders entered by a member organization that provides and accesses 0.05% or more of Consolidated Volume during the month—previously this required that the member organization provide an average daily volume of 100,000 or more. The Exchange believes the proposed rule change is reasonable because increasing this pricing incentive will provide meaningful incentives for members to increase their participation on the Exchange. The Exchange believes including ''accesses'' as part of the criteria will increase the quality of the market by allowing firms to decide how to participate most meaningfully on PSX. The requirement to provide and access 0.05% is reasonable because by achieving this activity level firms will be improving the market quality on PSX and thus receive a correspondingly higher credit than those firms that do not participate as actively on PSX. The Exchange also believes that the proposed rule change is consistent with an equitable allocation of fees and is not unfairly discriminatory because it affects all members equally and in the same way.

The Exchange also proposes to add a new tier for displayed quotes/orders. The new credit tier is $0.0023 per share executed for quotes/orders entered by a member organization that provides and accesses daily volume of 100,000 or more shares during the month. The Exchange believes the proposed rule change is reasonable because this new credit tier will provide an additional meaningful incentive for members to increase their participation on the Exchange. The Exchange also believes that the proposed rule change is consistent with an equitable allocation of fees and is not unfairly discriminatory because it affects all members equally and in the same way.

The Exchange believes that the proposed rule change to increase the credit to a member organization that executes in PSX for all other displayed quotes/orders from $0.0015 to $0.0020 per share executed is reasonable because increasing this pricing incentive will provide a meaningful incentive for members to increase their participation on the Exchange. The Exchange also believes that the proposed rule change is consistent with an equitable allocation of fees and is not unfairly discriminatory because it affects all members equally and in the same way.

The Exchange proposes to add another new tier for displayed quotes/orders size of 2,000 or more shares that will receive a $0.0001 credit in addition to the credits discussed above. Orders modified by the PSX participant entering the order or by the PSX System processes so that after such modification the unexecuted order size is below 2,000 shares will no longer qualify as an order of 2,000 or more shares. The Exchange believes the proposed rule change is reasonable because this new credit tier will provide an additional meaningful incentive for members to increase their participation on the Exchange. The Exchange also believes that the proposed rule change is consistent with an equitable allocation of fees and is not unfairly discriminatory because it affects all members equally and in the same way by allowing members to receive an additional $0.0001 credit per share executed in addition to the credits previously discussed by using relatively large orders of 2,000 or more shares.

The Exchange believes that the proposed rule change to add a new credit tier for non-displayed orders of $0.0015 per share executed for orders with midpoint pegging that provide liquidity entered by a member organization that provides 1,000,000 shares or more average daily volume of non-displayed liquidity during the month change is reasonable because this new credit tier will provide an additional meaningful incentive for members to increase their participation on the Exchange. The Exchange also believes that the proposed rule change is consistent with an equitable allocation of fees and is not unfairly discriminatory because the new credit tier is uniformly available to all members and affects all members equally and in the same way.

The Exchange also believes that the proposed rule change clarify that the credit tier for non-displayed orders of $0.0010 per share executed will continue to apply to all other orders with midpoint pegging that provide liquidity is reasonable because it clarifies the treatment of all other orders with midpoint pegging that provide liquidity with the addition of the new credit tier discussed in the paragraph immediately above. The Exchange also believes that the proposed rule change is consistent with an equitable allocation of fees and is not unfairly discriminatory because it affects all members equally and in the same way.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.[5] Phlx notes that it operates in a highly competitive market in which market participants can readily favor dozens of different competing exchanges and alternative trading systems if they deem charges at a particular venue to be excessive, or credit opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its charges and credits to remain competitive with other exchanges. Because competitors are free to modify their own charges and credits in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which changes to charges and credits in this market may impose any burden on competition is extremely limited.

In this instance, the changes to charges and credits do not impose a burden on competition because the Exchange membership is optional and is the subject of competition from other exchanges. The increased credits and charges are reflective of the intent to increase the order flow on the Exchange. For these reasons, the Exchange does not believe that any of the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets. Moreover, because there are numerous competitive alternatives to the use of the Exchange, it is likely that the Exchange will lose market share as a result of the changes if they are unattractive to market participants.

Accordingly, Phlx does not believe that the proposed rule changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section

[5] 15 U.S.C. 78f(b)(8).

19(b)(3)(A)(ii) of the Act.[6] 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–2015–45 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2015–45. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2015–45, and should be submitted on or before June 22, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–13072 Filed 5–29–15; 8:45 am]

BILLING CODE 8011–01–P

[6] 15 U.S.C. 78s(b)(3)(A)(ii).

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75042; File No. SR–NYSEArca–2015–18]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on Proposed Rule Change Relating to Listing and Trading Under NYSE Arca Equities Rule 5.2(j)(3), Commentary .02 of Shares of the Vanguard Tax-Exempt Bond Index Fund

May 26, 2015.

On April 6, 2015, NYSE Arca, Inc. filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade under NYSE Arca Equities Rule 5.2(j)(3), Commentary .02, the shares of the Vanguard Tax-Exempt Bond Index Fund. The proposed rule change was published for comment in the **Federal Register** on April 16, 2015.[3] The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act[4] provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The Commission is extending this 45-day time period. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change.

Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates July 15, 2015, as the date by which the Commission shall either approve or disapprove or institute proceedings to determine whether to disapprove the proposed rule change (File Number SR–NYSEArca–2015–18).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–13073 Filed 5–29–15; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 74701 (April 10, 2015), 80 FR 20529.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission Advisory Committee on Small and Emerging Companies will hold a public meeting on Wednesday, June 3, in Multi-Purpose Room LL–006 at the Commission's headquarters, 100 F Street NE., Washington, DC.

The meeting will begin at 9:30 a.m. (EDT) and will be open to the public. Seating will be on a first-come, first-served basis. Doors will open at 9:00 a.m. Visitors will be subject to security checks. The meeting will be webcast on the Commission's Web site at *www.sec.gov.*

On May 18, 2015, the Commission published notice of the Committee meeting (Release No. 33–9774), indicating that the meeting is open to the public and inviting the public to submit written comments to the Committee. This Sunshine Act notice is being issued because a majority of the Commission may attend the meeting.

The agenda for the meeting includes matters relating to rules and regulations affecting small and emerging companies under the federal securities laws.

For further information, please contact the Office of the Secretary at (202) 551–5400.

Dated: May 27, 2015.

Brent J. Fields,

Secretary.

[FR Doc. 2015–13322 Filed 5–28–15; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of America West Resources, Inc., Sonoma Valley Bancorp, and WorldStar Energy, Corp.; Order of Suspension of Trading

May 28, 2015.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of America West Resources, Inc. (CIK No. 867687), a Nevada corporation with its principal place of business listed as Salt Lake City, Utah, with stock quoted on OTC Link (previously, ''Pink Sheets'') operated by OTC Markets Group, Inc. (''OTC Link'') under the ticker symbol AWSRQ, because it has not filed any periodic reports since the period ended June 30, 2012. On September 13, 2013, America West Resources received a delinquency letter sent by the Division of Corporation Finance requesting compliance with their periodic filing obligations.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Sonoma Valley Bancorp (CIK No. 1120427), a California corporation with its principal place of business listed as Sonoma, California, with stock quoted on OTC Link under the ticker symbol SBNK, because it has not filed any periodic reports since the period ended June 30, 2010. On June 28, 2013, Sonoma Valley Bancorp received a delinquency letter sent by the Division of Corporation Finance requesting compliance with their periodic filing obligations.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of WorldStar Energy, Corp. (CIK No. 1093677), a revoked Nevada corporation with its principal place of business listed as Wanchai, Hong Kong, with stock quoted on OTC Link under the ticker symbol WSTR, because it has not filed any periodic reports since the period ended June 30, 2011. On May 29, 2013, WorldStar Energy received a delinquency letter sent by the Division of Corporation Finance requesting compliance with their periodic filing obligations.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed companies is suspended for the period from 9:30 a.m. EDT on May 28, 2015, through 11:59 p.m. EDT on June 10, 2015.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2015–13320 Filed 5–28–15; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75049; File No. SR–NYSEMKT–2015–22]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change Amending NYSEMKT Rule 13—Equities and Related Rules Governing Order Types and Modifiers

May 27, 2015.

On March 24, 2015, NYSE MKT LLC (''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 NYSEMKT Rule 13—Equities, and related NYSEMKT rules, governing order types and modifiers. The proposed rule change was published for comment in the **Federal Register** on April 14, 2015.[3] The Commission has received no comment letters regarding the proposed rule change.

Section 19(b)(2) of the Act [4] provides that, within 45 days of the publication of the notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The Commission is extending this 45-day time period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to section 19(b)(2) of the Act,[5] designates July 13, 2015 as the date by which the Commission should either approve or disapprove or institute proceedings to determine whether to disapprove the proposed rule change (File Number SR–NYSEMKT–2015–22).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–13172 Filed 5–29–15; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C.78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 74682 (April 8, 2015), 80 FR 20043 (''Notice'').

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

DEPARTMENT OF STATE

[Public Notice: 9155]

Advisory Committee on the Secretary of State's Strategic Dialogue With Civil Society; Notice of the Intent To Re-Establish an Advisory Committee

This is notice of the intent to re-establish the Advisory Committee on the Secretary of State's Strategic Dialogue with Civil Society. The Committee will serve the United States Government in a solely advisory capacity concerning engagement with and protection of civil society worldwide. Functions will include, but will not be limited to, providing information and advice on the effective integration of civil society into overall foreign policy, and providing information and advice on the Department of State's role in advancing, promoting, and protecting freedom of association and expression. The Department of State affirms that re-establishment of the Committee is necessary and in the public interest.

The Committee will consult with other interested parties, agencies, and interagency committees and groups of the United States Government, foreign governments, and with national and international private sector organizations and individuals, as the Department of State and the Committee decides are necessary or desirable.

The Committee will be comprised of up to twenty-four distinguished citizens from the private sector, philanthropy,

nongovernmental organizations, think tanks and academia, providing the Secretary with a fresh perspective and insight apart from and independent of the State Department organization. It will not perform the function of any existing Department staff or committee.

For further information, please contact the Committee's Designated Federal Officer, Jim Thompson, at *civilengagement@state.gov.*

Dated: May 23, 2015.

James F. Thompson,

Director of Innovation, Secretary's Office of Global Partnerships, U.S. Department of State.

[FR Doc. 2015–13115 Filed 5–29–15; 8:45 am]

BILLING CODE 4710–10–P

DEPARTMENT OF STATE

[Public Notice: 9156]

Notice of Meeting of Advisory Committee on International Law

A meeting of the Department of State's Advisory Committee on International Law will take place on Friday, June 26, from 9:30 a.m. to 5:00 p.m. at the George Washington University Law School, Michael K. Young Faculty Conference Center, 716 20th Street NW., 5th Floor, Washington, DC. Acting Legal Adviser Mary McLeod will chair the meeting, which will be open to the public up to the capacity of the conference room. The meeting will include discussions on a variety of international law topics.

Members of the public who wish to attend should contact the Office of the Legal Adviser by June 22 at *thorntonnc@state.gov* or 202–776–8356 and provide their name, professional affiliation, address, and phone number. A valid photo ID is required for admission to the meeting. Attendees who require reasonable accommodation should make their requests by June 19. Late requests will be considered but might not be possible to accommodate.

Dated: May 20, 2015.

Nicole C. Thornton,

Attorney-Adviser, Office of the Legal Adviser, Executive Director, Advisory Committee on International Law, United States Department of State.

[FR Doc. 2015–13114 Filed 5–29–15; 8:45 am]

BILLING CODE 4710–08–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA–2015–0016]

Agency Information Collection Activity Under OMB Review

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of request for comments.

SUMMARY: The Federal Transit Administration invites public comment about its intention to request the Office of Management and Budget's (OMB) approval to extend the approval of the following information collection:

49 U.S.C. Section 5316—Job Access and Reverse Commute (JARC) Program

The information collected is necessary to permit an assessment of program effectiveness and ensure the proper and timely expenditure of federal funds within the scope of the program. The **Federal Register** notice with a 60-day comment period soliciting comments for the (JARC) Program was published on March 15, 2015 (Citation 80 FR 51). No comments were received from that notice.

DATES: Comments must be submitted before July 1, 2015. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: All written comments must refer to the docket number that appears at the top of this document and be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention: FTA Desk Officer.

FOR FURTHER INFORMATION CONTACT: Tia Swain, Office of Administration, Office of Management Planning, (202) 366–0354.

SUPPLEMENTARY INFORMATION:

Title: Job Access and Reverse Commute Program

(*OMB Number: 2132–0563*)

Abstract: The Job Access and Reverse Commute (JARC) Program authorized federal funding to states for areas with a population of less than 200,000 and designated recipients in urbanized areas of 200,000 persons to address the unique transportation challenges faced by welfare recipients and low-income persons seeking to get and keep jobs. The (JARC) program has had a dramatic impact on the lives of thousands of welfare recipients and low-income families, helping individuals successfully transition from welfare to work and reach needed employment support services such as childcare and job training activities. On October 1, 2013, the (JARC) Program was repealed by Congress under the Moving Ahead for Progress in the 21st Century Act (MAP–21). However, to meet federal program oversight responsibilities, FTA must continue to collect information under the project management stage; until the period of availability expires; the funds are fully expended; the funds are rescinded by Congress; or the funds are otherwise reallocated.

Estimated Total Annual Burden: 52,080 hours.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Matthew M. Crouch,

Associate Administrator for Administration.

[FR Doc. 2015–13065 Filed 5–29–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2014–0107; Notice 2]

Continental Tire the Americas, LLC, Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition.

SUMMARY: Continental Tire the Americas, LLC (CTA) has determined that certain Continental General Altimax RT43 replacement tires do not fully comply with paragraphs S5.5(c) and (f) of Federal Motor Vehicle Safety Standard (FMVSS) No. 139, *New Pneumatic Radial Tires for Light Vehicles.* CTA has filed an appropriate report dated August 19, 2014, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.*

ADDRESSES: For further information on this decision contact Abraham Diaz, Office of Vehicle Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), telephone

(202) 366–5310, facsimile (202) 366–5930.

SUPPLEMENTARY INFORMATION:

I. *CTA's Petition:* Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), CTA submitted a petition for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

Notice of receipt of the petition was published, with a 30-day public comment period, on November 21, 2014 in the **Federal Register** (79 FR 69554). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) Web site at: *http://www.regulations.gov./.* Then follow the online search instructions to locate docket number ''NHTSA–2014–0107.''

II. *Tires Involved:* Affected are approximately 814 replacement tires that were manufactured for sale in the United States and Canada. CTA states that 181 of the replacement tires are still under their control. CTA further identified the tires as General Altimax RT43 brand 195/65R15 91T passenger car tires and General Altimax RT43 brand 195/65R15 91H passenger car tires.

III. *Noncompliance:* CTA explains that the noncompliance is that due to a mold labeling error the sidewall markings on both tires incorrectly describe the maximum inflation pressure as required by paragraph 5.5 (c) and the actual number plies in the tread area of the tires as required by paragraph S5.5(f) of FMVSS No. 139. Specifically, the 195/65R15 91T General Altimax RT43 tires were manufactured with ''Max Inflation Pressure: 350 kPa (51 PSI); Tread: 1 Polyester + 2 Steel + 2 Polyamide.'' The correct labeling and stamping should have been ''Max Inflation Pressure: 300 kPa (44 PSI); Tread: 1 Polyester + 2 Steel + 1 Polyamide.'' The 195/65R15 91H General Altimax RT43 tires were manufactured with ''Max Inflation Pressure 300 kPa (44 PSI); Tread: 1 Polyester + 2 Steel + 1 Polyamide.'' The correct labeling and stamping should have been ''Max Inflation Pressure 350 kPa (51 PSI); Tread: 1 Polyester + 2 Steel + 2 Polyamide.''

IV. *Rule Text:* Paragraph S5.5(c) and (f) of FMVSS No. 139 requires in pertinent part:

S5.5 Tire Markings. Except as specified in paragraphs (a) through (i) of S5.5, each tire must be marked on each sidewall with the information specified in S5.5(a) through (d) and on one sidewall with the information specified in S5.5(e) through (i) according to the phase-in schedule specified in S7 of this standard . . .

(C) The maximum permissible inflation pressure, subject to the limitation of S5.5.4 through S5.5.6 of this standard;

(f) The actual number of plies in the sidewall, and the actual number of plies in the tread area, if different;

V. *Summary of CTA's Analyses:* CTA stated its belief that the subject noncompliance is inconsequential to motor vehicle safety for the following reasons:

(A) Number of Plies: CTA believes that the mislabeling of the number of plies on the subject tires has no impact on the operational performance of the subject tires or on the safety of vehicles on which these tires are to be mounted. CTA states that the subject tires also meet or exceed all of the performance requirements specified by FMVSS No. 139.

(B) Max Inflation Pressure: CTA believes that the choice of the maximum inflation pressure level is the decision of the tire manufacturer, as long as it is in compliance with the established values under FMVSS No. 139 paragraph S5.5.4. CTA also believes that the maximum inflation pressure values of 350 kPa and 300 kPa on both tires are acceptable choices and stated that both tires can accommodate a maximum pressure of 350 kPa (51 PSI).

(C) Overloading: CTA believes that the use of either of the maximum inflation pressures displayed on the subject tire sidewalls as the source of information for the recommended inflation pressure will not result in an overloading of the tires or their load carrying capacity. CTA says this is because both values (300 kPa and 350 kPa) are above the inflation pressure of 250 kPa (36 PSI) at which the tire's maximum load capacity is defined by the European Tyre and Rim Technical Organisation (ETRTO) standard.

(D) Strength: CTA stated that each standard load tire has a specified tire strength requirement which is defined in paragraph S6.5 of FMVSS No. 139 (and paragraph S5.3 of FMVSS No. 109) and must be met whether the selected maximum permissible pressure marking value is 240 kPa (35 PSI), 300 kPa (44 PSI), or 350 kPa (51 PSI). CTA believes that both of the subject tires meet this requirement.

(E) Incidents: CTA stated that they are not aware of any crashes, injuries, customer complaints, or field reports associated with the subject noncompliance.

(F) Previous Rulings: CTA made mention that NHTSA has previously granted tire companies inconsequentiality exemptions relating to errors in sidewall markings.

CTA has additionally informed NHTSA that it has corrected the noncompliance so that all future production of the subject tires comply with FMVSS No. 139.

In summation, CTA believes that the described noncompliance of the subject tires is inconsequential to motor vehicle safety, and that its petition, to exempt CTA from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120 should be granted.

NHTSA Decision

NHTSA Analysis: Continental explained that the subject tires, the 195/65R15 91T General Altimax RT43 and the 195/65R15 91H General Altimax RT43, do not comply with paragraph S5.5(c) FMVSS No. 139 because they were manufactured with an incorrect maximum permissible inflation pressure value. The maximum permissible inflation pressure for the 195/65R15 91T General Altimax RT43 was marked as 350 KPA (51 PSI)and the maximum permissible inflation pressure for the 195/65R15 91H General Altimax RT43 was marked as 300 KPA (44 PSI). The correct maximum permissible inflation pressure value for the 195/65R15 91T General Altimax RT43 should have been 300 KPA (44 PSI) while the correct maximum inflation pressure for the 195/65R15 91H General Altimax RT43 should have been 350 KPA (51 PSI). Continental stated that for the subject 195/65R15 standard load tires, both maximum inflation pressures of 350 KPA and 300 KPA are acceptable choices and both types of tires can safely accommodate the maximum inflation pressure of 350 KPA.

Continental stated that inflation of the tires to the incorrect maximum pressure value stamped on the sidewall will not result in overloading of their load carrying capacity since both values of 300 KPA and 350 KPA are above the inflation pressure of 250 KPA at which the tire's maximum load capacity is defined by the European Tyre and Rim Technical Organisation (ETRTO). Thus, the maximum load capacity of these tires can be obtained with the stamped pressures of 300 KPA and 350 KPA and therefore following the maximum permissible inflation pressure values on the side wall of the tires will not lead to inadvertent overloading.

NHTSA agrees that in the case of the subject tires the noncompliances with paragraph S5.5(c) of FMVSS No. 139 are inconsequential to motor vehicle safety.

The mislabeling does not cause any safety problems, such as increasing the probability of tire failure, and it is unlikely to result in unsafe use of the tires.

The agency also believes that the noncompliance of the subject tires with the ply labeling requirements of paragraph S5.5(f) of FMVSS No. 139 is inconsequential to motor vehicle safety because the noncompliance does not affect the operational safety of the vehicles on which these tires are mounted. Although tire construction affects the strength and durability, information relating tire strength and durability to the number of plies and types of ply cord material in the tread and sidewall is not readily available to tire dealers and consumers. Therefore, tire dealers and consumers should consider the tire construction information along with other information such as load capacity, maximum inflation pressure, and tread wear, temperature, and traction ratings, to assess performance capabilities of various tires. In the agency's judgment, the incorrect labeling of the tire construction information will have an inconsequential effect on motor vehicle safety because most consumers do not base tire purchases or vehicle operation parameters on the number of plies in a tire.

NHTSA has also considered the safety of personnel working in the tire retread, repair, and recycling industries in assessing whether the noncompliance of the subject tires with paragraph S5.5(f) FMVSS No. 139 is inconsequential to motor vehicle safety. The agency believes the noncompliance will have no measurable effect on the safety of tire retread, repair, and recycling industries. The use of steel cord construction in the sidewall and tread is the primary safety concern of these industries. In this case, since the tire sidewall is marked correctly for the number of steel plies, this potential safety concern does not exist.

NHTSA Decision: In consideration of the foregoing, NHTSA has decided that CTA has met its burden of persuasion that the FMVSS No. 139 noncompliance is inconsequential to motor vehicle safety. Accordingly, CTA's petition is hereby granted and CTA is exempted from the obligation of providing notification of, and a remedy for, that noncompliance under 49 U.S.C. 30118 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the subject noncompliant tires that CTA no longer controlled at the time it determined that the noncompliance existed. However, the granting of this petition does not relieve equipment distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant tires under their control after CTA notified them that the subject noncompliance existed.

Authority: (49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8)

Jeffrey M. Giuseppe,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2015–13109 Filed 5–29–15; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. AB 290 (Sub-No. 377X)]; [Docket No. AB 1231X]

Norfolk Southern Railway Company—Discontinuance of Service Exemption—in Lucas County, Ohio; Midwest Rail, LLC d/b/a/Toledo, Lake Erie and Western Railway—Discontinuance of Service Exemption—in Lucas County, Ohio

Norfolk Southern Railway Company (NSR) and Midwest Rail, LLC d/b/a Toledo, Lake Erie and Western Railway (TLEW) (collectively, applicants) have jointly filed a verified notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments and Discontinuances of Service* for NSR to discontinue rail service, and for TLEW to discontinue lease operations, over approximately 1.80-miles of rail line owned by NSR between milepost TS 13.2 near Maumee, to milepost TS 15.0 at Waterville, in Lucas County, Ohio (the Line). Applicants state that TLEW originally obtained authority to operate the Line in 2012; [1] however, TLEW did not conduct any business on the Line and eventually defaulted on the lease. Thereafter, NSR cancelled the lease pursuant to the terms of the parties' contract, and NSR has been given power of attorney to file for discontinuance of TLEW's lease operations on TLEW's behalf. The Line traverses United States Postal Service Zip Codes 43537 and 43566.

Applicants have certified that: (1) No local traffic has moved over the Line for at least two years; (2) no overhead traffic has moved over the Line for at least two years and overhead traffic, if any, could be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line either is pending with the Surface Transportation Board or with any U.S. District Court or has been decided in favor of complainant within the two-year period; and (4) the requirements at 49 CFR 1105.12 (newspaper publication) and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to these exemptions, any employee adversely affected by the discontinuance of service shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) to subsidize continued rail service has been received, these exemptions will be effective on July 1, 2015, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues and formal expressions of intent to file an OFA to subsidize continued rail service under 49 CFR 1152.27(c)(2) [2] must be filed by June 11, 2015.[3] Petitions to reopen must be filed by June 22, 2015, with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to applicants' representative: William A. Mullins, Baker & Miller PLLC, 2401 Pennsylvania Ave. NW., Suite 300, Washington, DC 20037.

If the notice contains false or misleading information, these exemptions are void *ab initio.*

Board decisions and notices are available on our Web site at ''*www.stb.dot.gov.*''

[1] *Midwest Rail, LLC d/b/a Toledo, Lake Erie & W. Ry.—Lease & Operation Exemption—Norfolk S. Ry.,* FD 35634 (STB served June 29, 2012).

[2] Each OFA must be accompanied by the filing fee, which is currently set at $1,600. *See* 49 CFR 1002.2(f)(25).

[3] Because applicants are seeking to discontinue service, not to abandon the Line, trail use/rail banking and public use conditions are not appropriate.

Decided: May 27, 2015.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Brendetta S. Jones,

Clearance Clerk.

[FR Doc. 2015–13096 Filed 5–29–15; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Privacy Act of 1974, as Amended

AGENCY: Office of the Comptroller of the Currency, Treasury.

ACTION: Notice of proposed new Privacy Act system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a, the Office of the Comptroller of the Currency (OCC) gives notice of a proposed new system of records entitled ''Treasury/CC .800—Office of Inspector General Investigations System.''

DATES: Comments must be received no later than July 1, 2015. This new system of records will be effective July 6, 2015 unless the OCC receives comments that would result in a contrary determination.

ADDRESSES: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible. Please use the title ''Notice of Proposed New Privacy Act System of Records'' to facilitate the organization and distribution of the comments. You may submit comments by any of the following methods:

- *Email: regs.comments@occ.treas.gov.*
- *Mail:* Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and the docket number in your comment. In general, OCC will enter all comments received into the docket without change, including any business or personal information that you provide such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this notice by appearing personally to inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

FOR FURTHER INFORMATION CONTACT: Kristin Merritt, Special Counsel, Administrative and Internal Law, Office of the Comptroller of the Currency, 400 7th Street SW., Washington, DC 20219. Phone: (202) 649–5585 (not a toll-free number).

SUPPLEMENTARY INFORMATION: By this notice, the OCC announces its intent to maintain a new Privacy Act system of records in its Office of Enterprise Governance and the Ombudsman.

A proposed rule exempting the proposed system of records from certain provisions of the Privacy Act pursuant to 5 U.S.C. 552a(k)(2) will be published separately in the **Federal Register**.

As required by 5 U.S.C. 552a(r), a report of a new system of records has been provided to the Committee on Oversight and Government Reform of the House of Representatives, the Committee on Homeland Security and Governmental Affairs of the Senate, and the Office of Management and Budget.

The system of records entitled ''Treasury/CC .800—Office of Inspector General Investigations System'' is published in its entirety below.

Helen Goff Foster,

Deputy Assistant Secretary for Privacy, Transparency, and Records.

Treasury/CC .800

SYSTEM NAME:

Office of Inspector General Investigations System

SYSTEM LOCATION:

OCC Headquarters, Office of Enterprise Governance and the Ombudsman, 400 7th Street SW., Washington, DC.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

(1) Current and former OCC employees who are being investigated by the Treasury Office of the Inspector General;

(2) Current and former OCC contractors who are being investigated by the Treasury Office of the Inspector General (OIG); and

(3) Current and former directors, officers, employees, shareholders, and independent contractors of financial institutions who are being investigated by the OIG.

CATEGORIES OF RECORDS IN THE SYSTEM:

Referrals regarding potential or alleged violations of laws, rules or regulations; names of targets, complainants, managers, Enterprise Governance staff and other government employees who may be named in referral or investigative documents; documents regarding resolutions and remedial action in connection with referrals; other supporting documentation, including bank-related information, investigative documentation, and correspondence related to investigations.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. App. 3; 12 U.S.C. 1, as amended; 31 CFR 0.207.

PURPOSES(S):

This system of records is used by the OCC to monitor the OIG's referrals and investigations related to the OCC.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Records in this system may be disclosed to:

(1) An OCC-regulated entity when the information is relevant to the entity's operations;

(2) Third parties to the extent necessary to obtain information that is relevant to an investigation;

(3) Appropriate governmental or self-regulatory organizations when the OCC determines that the records are relevant and necessary to the governmental or self-regulatory organization's regulation and supervision of financial service providers, including the review of the qualifications and fitness of individuals who are or propose to become responsible for the business operations of such providers;

(4) An appropriate governmental, international, tribal, self-regulatory, or professional organization if the information is relevant to a known or suspected violation of a law or licensing standard within that organization's jurisdiction;

(5) A Federal, State, local, or tribal agency, or other public authority, which has requested information relevant or necessary to hiring or retaining an

employee, or issuing or continuing a contract, security clearance, license, grant, or other benefit;

(6) The Department of Justice, a court, an adjudicative body, a party in litigation, or a witness if the OCC determines that the information is relevant and necessary to a proceeding in which the OCC, any OCC employee in his or her official capacity, any OCC employee in his or her individual capacity represented by the Department of Justice or the OCC, or the United States is a party or has an interest;

(7) A congressional office when the information is relevant to an inquiry made at the request of the individual about whom the record is maintained;

(8) A contractor or agent who needs to have access to this system of records to perform an assigned activity;

(9) Third parties when mandated or authorized by statute; or

(10) Appropriate agencies, entities, and persons when: (a) The OCC suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (b) the OCC 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 the OCC or another agency or entity) that rely upon the compromised information; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the OCC's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records and electronic media.

RETRIEVABILITY:

Records may be retrieved by name; social security number; OIG tracking number; the date a referral is received, transmitted or closed; another personal identifier of person about whom a referral is made; or by OCC employee name or identification number for the employee assigned to a particular matter.

SAFEGUARDS:

Paper records are maintained in locked file cabinets with access limited to those personnel whose official duties require access. Access to electronic systems is restricted to authorized personnel who are issued non-transferrable access codes and passwords.

RETENTION AND DISPOSAL:

Records will be retained for 7 years, and the office of Enterprise Governance and the Ombudsman will destroy records older than 7 years in accordance with OCC Records Retention Schedule item 1.2c (7-year project files), and continue to do so annually.

SYSTEM MANAGER(S) AND ADDRESS:

Senior Deputy Comptroller for Enterprise Governance and the Ombudsman, 400 7th Street SW., Washington, DC 20219. Phone: (202) 649–5530 (not a toll-free number).

NOTIFICATION PROCEDURE:

This system of records contains records that are exempt from the notification, access and contest requirements pursuant to 5 U.S.C. 552a(k)(2). Individuals seeking notification and access to any non-exempt record contained in this system of records, or seeking to contest its content, may inquire in writing in accordance with instructions appearing at 31 CFR, Part 1, subpart C, and appendix J to subpart C. Written inquiries should be addressed to Disclosure Officer, Communications Division, Office of the Comptroller of the Currency, 400 7th Street SW., Washington, DC 20219.

Identification requirements: An individual seeking notification through the mail must establish his or her identity by providing a signature and an address as well as one other identifier bearing the individual's name and signature (such as a photocopy of a driver's license or other official document). An individual seeking notification in person must establish his or her identity by providing proof in the form of a single official document bearing a photograph (such as a passport or identification badge) or two items of identification that bear both a name and a signature.

Alternatively, identity may be established by providing a notarized statement, swearing or affirming to an individual's identify, and to the fact that the individual understands the penalties provided in 5 U.S.C. 552a(i)(3) for requesting or obtaining information under false pretenses.

Additional documentation establishing identity or qualification for notification may be required such as in an instance where a legal guardian or representative seeks notification on behalf of another individual.

RECORD ACCESS PROCEDURES:

See ''Notification Procedure'' above.

CONTESTING RECORDS PROCEDURES:

See ''Notification Procedure'' above.

RECORD SOURCE CATEGORIES:

Treasury and other Federal agency records, including referrals from the OCC to the OIG and referrals received from the OIG.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Some of the records in this system are exempt from sections 5 U.S.C. 552a(c)(3), (d)(1)–(4), (e)(1), (e)(4)(G)–(I), and, (f) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(2). See 31 CFR 1.36.

[FR Doc. 2015–13165 Filed 5–29–15; 8:45 am]

BILLING CODE 4810–33–P

FEDERAL REGISTER

Vol. 80 Monday,
No. 104 June 1, 2015

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 431, 433, 438, *et al.*
Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 431, 433, 438, 440, 457 and 495

[CMS–2390–P]

RIN 0938–AS25

Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would modernize the Medicaid managed care regulations to reflect changes in the usage of managed care delivery systems. The proposed rule would align the rules governing Medicaid managed care with those of other major sources of coverage, including coverage through Qualified Health Plans and Medicare Advantage plans; implement statutory provisions; strengthen actuarial soundness payment provisions to promote the accountability of Medicaid managed care program rates; and promote the quality of care and strengthen efforts to reform delivery systems that serve Medicaid and CHIP beneficiaries. It would also ensure appropriate beneficiary protections and enhance policies related to program integrity. This proposed rule would also require states to establish comprehensive quality strategies for their Medicaid and CHIP programs regardless of how services are provided to beneficiaries. This proposed rule would also implement provisions of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) and addresses third party liability for trauma codes.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 27, 2015.

ADDRESSES: In commenting, please refer to file code CMS–2390–P. 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–2390–P, P.O. Box 8016, Baltimore, MD 21244–8016.

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–2390–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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) 786–7195 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:

Nicole Kaufman, (410) 786–6604, Medicaid Managed Care Operations.

Kristin Younger, (410) 786–3869, Medicaid Managed Care Quality.

Meg Barry, (410) 786–1536, CHIP.

Nancy Dieter, (410) 786–7219, Third Party Liability.

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 would also be 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.

Table of Contents

Acronyms

Because of the many organizations and terms to which we refer by acronym in this proposed rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

[the] Act Social Security Act
Affordable Care Act The Affordable Care Act of 2010 (which is the collective term for the Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care Education Reconciliation Act (Pub. L. 111–152))
ARRA American Recovery and Reinvestment Act of 2009
BBA Balanced Budget Act of 1997
BIA Bureau of Indian Affairs
CDIB Certificate of Degree of Indian Blood
CPE Certified Public Expenditure
CFR Code of Federal Regulations
CBE Community Benefit Expenditures
CHIP Children's Health Insurance Program
CHIPRA Children's Health Insurance Program Reauthorization Act of 2009
CMS Centers for Medicare & Medicaid Services
DUR Drug Utilization Review [program]
EQR External Quality Review
EQRO External Quality Review Organization
FFM Federally-Facilitated Marketplaces
FFP Federal Financial Participation
FFS Fee-For-Service
FMAP Federal Medical Assistance Percentage
FQHC Federally Qualified Health Center
FY Fiscal Year
HHS [U.S. Department of] Health and Human Services
HIO Health Insuring Organization
HIPAA Health Insurance Portability and Accountability Act of 1996
ICD International Classification of Diseases
IGT Intergovernmental Transfer
IHCP Indian Health Care Provider
LEP Limited English Proficiency
LTSS Long-Term Services and Supports
MA Medicare Advantage
MACPAC Medicaid and CHIP Payment and Access Commission
MCO Managed Care Organization
MFCU Medicaid Fraud Control Unit
MHPA Mental Health Parity Act of 1996
MHPAEA Mental Health Parity and Addiction Equity Act MHPAEA
MLTSS Managed Long-Term Services and Supports
MLR Medical Loss Ratio
MSIS Medicaid Statistical Information System
MH/SUD Mental Health/Substance Use Disorder Services
NAMD National Association of Medicaid Directors
NCQA National Committee for Quality Assurance
NEMT Non-Emergency Medical Transportation
OMB Office of Management and Budget
PCCM Primary Care Case Manager
PHS Public Health Service Act
PIP Performance Improvement Project
PMPM Per-member Per-month
PAHP Pre-paid Ambulatory Health Plan
PIHP Pre-paid Inpatient Health Plan
QHP Qualified Health Plans
SHO State Health Official Letter
SBC Summary of Benefits and Coverage
SFH State Fair Hearing
SBM State-Based Marketplaces
SIU Special Investigation Unit
SMDL State Medicaid Director Letter
T–MSIS Transformed Medicaid Statistical Information System
TPL Third Party Liability

I. Medicaid Managed Care

A. Background

In 1965, amendments to the Social Security Act (the Act) established the Medicaid program as a joint federal and state program to provide medical assistance to individuals with low incomes. Under the Medicaid program, each state that chooses to participate in the program and receive federal financial participation for program expenditures establishes eligibility standards, benefits packages, and payment rates, and undertakes program administration in accordance with federal statutory and regulatory standards. The provisions of each state's Medicaid program are described in the state's Medicaid ''state plan.'' Among other responsibilities, we approve state plans and monitor activities and expenditures for compliance with federal Medicaid laws to ensure that beneficiaries receive access to quality health care. (Throughout this preamble, we use the term ''beneficiaries'' to mean ''individuals eligible for and receiving Medicaid benefits.'')

Until the early 1990s, most Medicaid beneficiaries received Medicaid coverage through fee-for-service (FFS) arrangements. However, over time that practice has shifted and states are increasingly utilizing managed care arrangements to provide Medicaid coverage to beneficiaries. Under managed care, beneficiaries receive part or all of their Medicaid services from health care providers who are paid by an organization that is under contract with the state; the organization receives a monthly capitated payment for a specified benefit package. In 1992, 2.4 million Medicaid beneficiaries (or 8 percent of all Medicaid beneficiaries) accessed part or all of their Medicaid benefits through capitated health plans; by 1998, that number had increased fivefold to 12.6 million (or 41 percent of all Medicaid beneficiaries). In fiscal year (FY) 2011, at least 39 million (or 58 percent of all Medicaid beneficiaries) in 39 states and the District of Columbia accessed part or all of their Medicaid benefits through such capitated health plans.[1]

In a Medicaid managed care delivery system, through contracts with health plans, states require that the plan provide or arrange for a specified package of Medicaid services for

[1] MACPAC, *Report to Congress on Medicaid and CHIP* (June 2014), tables 11 and 14 at pgs. 106 and 120, available at *https://www.macpac.gov/wp-content/uploads/2015/01/2014-06-13_MACPAC_Report.pdf*.

enrolled beneficiaries. Under these contracts, the organization offering the health plan is paid a fixed, prospective, monthly payment for each enrolled beneficiary. This payment approach is referred to as ''capitation.'' Beneficiaries enrolled in capitated managed care organizations (MCOs) must access the Medicaid services covered under the state plan through the health plan. States may contract with managed care entities that offer comprehensive benefits, referred to as MCOs. Alternatively, managed care plans can receive a capitated payment for a limited array of services, such as behavioral health or dental services. Such entities that receive a capitated payment for a limited array of services are referred to as ''prepaid inpatient health plans'' (PIHPs) or ''prepaid ambulatory health plans'' (PAHPs) depending on the scope of services the health plan provides. Finally, applicable federal statute recognizes primary care case management as a type of managed care entity subject to some of the same standards as MCOs. States that do not pursue capitated arrangements but want to promote coordination and care management may contract with primary care providers or care management entities to support better health outcomes and increase the quality of care delivered to beneficiaries, but continue to pay for covered benefits on a FFS basis directly to the health care provider.

As Medicaid managed care grew in the 1990's, the Congress enacted specific standards for Medicaid managed care programs in sections 4701 through 4709 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted on August 5, 1997). The BBA represented the first comprehensive revision to federal statutes governing Medicaid managed care since the early 1980s. In general, the BBA modified the federal statute to: (1) Allow states to mandate the enrollment of certain Medicaid beneficiaries into MCOs without having to first seek a waiver of federal statutory standards; (2) eliminate standards on the composition of enrollment in MCOs that had not proven to be effective (the 75/25 rule limiting Medicare and Medicaid enrollment to 75 percent of total enrollment); (3) apply consumer protections that were becoming widespread in the private sector and Medicare markets to Medicaid beneficiaries (for example, consumer information standards and standards for access to services); and (4) apply certain advances and developments in health care quality improvement that were then widely used in the private sector to Medicaid managed care programs. These standards are codified in sections 1903 and 1932 of the Act and implemented in regulations at 42 CFR part 438 published June 14, 2002 (67 FR 40989), with an effective date of August 13, 2002.

Since the publication of the Medicaid managed care regulations in 2002, the landscape for health care delivery has continued to change, both within the Medicaid program and outside (in Medicare and the private sector market). States have continued to expand the use of managed care over the past decade, serving both new geographic areas and broader groups of Medicaid beneficiaries. In particular, states have expanded managed care delivery systems to include seniors and persons with disabilities, as well as those who need long-term services and supports (LTSS). In 2004, eight states (AZ, FL, MA, MI, MN, NY, TX, and WI) had implemented Medicaid managed long-term services and supports (MLTSS) programs. By January 2014, 12 additional states had implemented MLTSS programs (CA, DE, IL, KS, NC, NM, OH, PA, RI, TN, VA, WA).

The predominant form of managed care in Medicaid is capitated risk-based arrangements—virtually identical in structure and payment to arrangements in the commercial marketplace. Notably, in FY 2011, at least 58 percent of all Medicaid beneficiaries (about 39 million individuals) in 39 states and the District of Columbia accessed part or all of their Medicaid benefits through such capitated health plans, accounting for approximately 24 percent of all Medicaid spending. These figures are based on the Medicaid and CHIP Payment and Access Commission (MACPAC) Report to Congress on Medicaid and CHIP (June 2014).[2] Some states carve out behavioral health or dental services from the comprehensive acute care MCO and manage such services under a risk-based PIHP or PAHP. Additional states have added or expanded managed care programs since 2012.

States may implement a managed care delivery system using four types of federal authorities. Under the authority of section 1915(a) of the Act, states can implement a voluntary managed care program by executing a contract with organizations that the state has procured using a competitive procurement process. To require beneficiaries to enroll in managed care to receive services, a state must obtain approval from CMS under two primary authorities:

(1) Through a state plan amendment that meets standards set forth in section 1932 of the Act, states can implement a mandatory managed care delivery system. This authority does not allow states to require beneficiaries who are dually eligible for Medicare and Medicaid (dually eligible), American Indians/Alaska Natives, or children with special health care needs to enroll in a managed care program. State plans, once approved, remain in effect until modified by the state.

(2) CMS may grant a waiver under section 1915(b) of the Act, permitting a state to require all Medicaid beneficiaries to enroll in a managed care delivery system, including dually eligible beneficiaries, American Indians/Alaska Natives, or children with special health care needs. After approval, a state may operate a section 1915(b) waiver for a 2-year period (certain waivers can be operated for up to 5 years if they include dually eligible beneficiaries) before requesting a renewal for an additional 2 (or 5) year period.

CMS may also authorize managed care programs as part of demonstration projects under section 1115(a) of the Act that includes waivers permitting the state to require all Medicaid beneficiaries to enroll in a managed care delivery system, including dually eligible beneficiaries, American Indians/Alaska Natives, and children with special health care needs. Under this authority, states may seek additional flexibility to demonstrate and evaluate innovative policy approaches for delivering Medicaid benefits, as well as the option to provide services not typically covered by Medicaid. Such flexibility is approvable only if the objectives of the Medicaid statute are likely to be met, and is subject to evaluation.

These authorities may permit states to operate their programs without complying with the following standards of Medicaid law outlined in section of 1902 of the Act:

- Statewideness [section 1902(a)(1) of the Act]: States may implement a managed care delivery system in specific areas of the State (generally counties/parishes) rather than the whole state;
- Comparability of Services [section 1902(a)(10) of the Act]: States may provide different benefits to people enrolled in a managed care delivery system; and
- Freedom of Choice [section 1902(a)(23)(A) of the Act]: States may

[2] MACPAC, *Report to Congress on Medicaid and CHIP* (June 2014) at pgs. 106, 119, and 120, available at *https://www.macpac.gov/wp-content/uploads/2015/01/2014-06-13_MACPAC_Report.pdf.*

require people to receive their Medicaid services only from a managed care plan or primary care provider.

Laws passed since the Medicaid managed care regulations were promulgated in 2002 have altered the Medicaid program to such a degree that we believe our current regulatory framework for managed care is no longer the most appropriate. Such legislation includes the Medicare Improvement for Patients and Providers Act (MIPPA) (Pub. L. 110–275, enacted on July 15, 2008), the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (sections 511 and 512 of the Tax Extenders and Alternative Minimum Tax Relief Act of 2008) (MHPAEA) (Division C of Pub. L. 110–343, enacted on October 3, 2008), the Children's Health Insurance Program Reauthorization Act (CHIPRA) (Pub. L. 111–3, enacted on February 4, 2009), and the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) (Pub. L. 111–148, enacted March 23, 2010). We note, in particular, that the Affordable Care Act provided states the option to expand Medicaid eligibility to most low-income adults, bringing millions of new beneficiaries into the Medicaid program, most of whom are likely to receive coverage through capitated managed care. In addition, the coverage provided under the Affordable Care Act has also made issues of coordination and alignment with the private insurance market increasingly important to improve operational efficiencies for health plans that operate in both public and private markets, and improve the experience of care for individuals moving between sources of health care coverage. Specifically, Medicaid beneficiaries who experience increases in income may move to receiving health insurance coverage through qualified health plans in the Marketplace. Greater alignment between Medicaid managed care plans and qualified health plans will help these individuals transition between sources of coverage.

Because the health care delivery landscape has changed substantially, both within the Medicaid program and outside of it, and reflecting the significant role that managed care plays in the Medicaid program, this rule proposes to modernize the Medicaid managed care regulatory structure to facilitate and support delivery system reform initiatives to improve health care outcomes and the beneficiary experience while effectively managing costs. To that end, the proposed rule includes provisions that would strengthen the ability of states to use managed care to promote innovative and cost effective methods of delivering care to Medicaid and CHIP beneficiaries, to incent managed care plans to engage in state activities that promote certain performance targets, and to identify strategies for value-based purchasing models for provider reimbursement. The rule also includes provisions that strengthen the quality of care provided to Medicaid beneficiaries, including measuring and managing quality and improving coordination of care. The rule also promotes more effective use of data in overseeing managed care and promotes advances in health information exchange.

This proposed rule would revise the Medicaid managed care regulations to align with other statutory and regulatory provisions that pertain to other sources of coverage, strengthen actuarial soundness and other payment regulations to improve accountability of rates paid in the Medicaid managed care program, ensure beneficiary protections, and incorporate statutory provisions affecting Medicaid managed care passed since 2002. In addition, the rule promotes beneficiary access to care by strengthening provider networks. This proposed rule also recognizes that through managed care plans, state and federal taxpayer dollars are used to purchase covered services from providers on behalf of Medicaid enrollees, thus ensuring accountability and strengthening program integrity safeguards are necessary to ensure the appropriate stewardship of those funds.

We recognize that in addition to the changes the Affordable Care Act brought to the Medicaid program, it also included significant changes for private insurance and group health plans. Among the reforms of the private health care coverage market are the creation of minimum standards for the treatment of appeals by covered individuals, minimum medical loss ratios for health insurance, and certain minimum coverage standards for essential health benefits and preventive services. The Affordable Care Act created the Marketplaces (also known as ''Exchanges'') and qualified health plans (QHPs), which are private health plans that are certified as meeting minimum standards. *See* 45 CFR 155.20. Only QHPs can be offered through Marketplaces and they are the only plans for which federal premium tax credits and cost-sharing reductions are available to assist many consumers with the cost of health care coverage. In developing these Medicaid managed care proposed regulations, we considered the market reforms, the standards established for QHPs, and our Medicare Advantage (MA) experience, which is the managed care component of the Medicare program that has also grown significantly since 2002.

Therefore, this proposed rule seeks to align Medicaid managed care rules with Marketplace or MA standards, where appropriate and feasible, to support administrative simplicity for states and health plans to manage health care delivery across different product lines, as well as to enhance beneficiary protections. In general, we believe that adopting standards for Medicaid managed care that parallel or align with those in the private health care and MA context where appropriate will benefit Medicaid programs and enrollees, both because those minimum standards would provide an appropriate level of protection for enrollees and because alignment would ease the administrative burden on issuers and regulators that work in all of those contexts and markets. By aligning Medicaid managed care with other programs when possible, we believe enrollees will experience smoother transitions and have fewer disruptions to care when they transition among sources of health care coverage. Improving beneficiary experience and alignment are important goals of this proposed rule, and the proposed changes would enable states and health plans to more successfully achieve these goals.

B. Provisions of the Proposed Regulations

We have restated the entirety of part 438 and incorporated our proposed changes into the regulation text due to the extensive nature of our proposal. However, for many sections within part 438, we are not proposing substantive changes. This preamble discusses our proposed changes with discussion of the current law where appropriate.

Throughout this document, the term ''PAHP'' is used to mean a prepaid ambulatory health plan that does not exclusively provide non-emergency medical transportation services. Whenever this document is referencing a PAHP that exclusively provides non-emergency medical transportation services, it will be specifically addressed as a ''Non-Emergency Medical Transportation (NEMT) PAHP.'' In addition, many of our proposals incorporate ''PCCM entities'' into existing regulatory provisions and the proposed amendments. Our proposal on this topic is discussed in section I.B.6.e. of this proposed rule.

In general, we have organized the subjects in this proposed rule according to one of the goals described above, but

many of the subjects could be attributed to more than one goal.

1. Alignment With Other Health Coverage Programs

a. Marketing (§ 438.104)

Current regulation at § 438.104 imposes certain limits on MCOs, PIHPs, PAHPs, and PCCMs in connection with marketing activities; our 2002 final rule based these limits on those set forth in section 1932(d)(2) of the Act for MCOs and PCCMs and extended them to PIHPs and PAHPs based on our authority at section 1902(a)(4) of the Act. The creation of qualified health plans (QHPs) by the Affordable Care Act and changes in managed care delivery systems since the adoption of the 2002 rule are the principle reasons behind our proposal to revise the marketing standards applicable to Medicaid managed care programs. QHPs are defined in 45 CFR 155.20.

We propose to revise § 438.104(a) as follows: To (1) to amend the definition of ''marketing'' in § 438.104 to specifically exclude communications from a QHP to Medicaid beneficiaries even if the issuer of the QHP is also the entity providing Medicaid managed care; (2) to amend the definition of ''marketing materials;'' and (3) to add a definition for ''private insurance'' to clarify that QHPs certified for participation in the FFM or an SBM are excluded from the term ''private insurance'' as it is used in this regulation. In recognition of the wide array of services PCCM entities provide in some markets, we also propose to include PCCM entities in § 438.104 as we believe it is important to extend the beneficiary protections afforded by this section to enrollees of PCCM entity enrollees by proposing to revise paragraphs (a) and (b) to include ''or PCCM entity'' wherever the phrase ''MCO, PIHP, PAHP or PCCM'' appears. We are not proposing changes to paragraph (b), except for one clarifying change to (b)(1)(v) as noted below.

We have received several questions from Medicaid managed care plans about the implications of current Medicaid marketing rules in § 438.104 for their operation of QHPs. Specifically, stakeholders have asked whether the provisions of § 438.104(b)(1)(iv) would prohibit a carrier that offers both a qualified health plan (QHP) and a managed care organization (MCO) from marketing both products. The provision in the regulations implements section 1932(d)(2)(C) of the Act, titled ''Prohibition of Tie-Ins.'' In issuing regulations implementing this provision in 2002, we clarified that we interpreted it as intended to preclude tying enrollment in the Medicaid plan to purchasing other types of private insurance (67 FR 41027). Therefore, it would not apply to the issue of a possible alternative to the Medicaid plan, which a QHP could be if the consumer is determined as not Medicaid eligible or loses Medicaid eligibility. Section 438.104(b)(1)(iv) only prohibits insurance policies that would be sold ''in conjunction with'' enrollment in the Medicaid plan.

We recognize that a single legal entity could be operating separate lines of business, that is, a Medicaid MCO (or PIHP or PAHP) and a QHP. Issuers of QHPs may also contract with states to provide Medicaid managed care plans; in some cases the issuer might be the MCO, PIHP, or PAHP, or the entity offering the Medicaid managed care plan, thus providing coverage to Medicaid beneficiaries. Many Medicaid health plan contracts with states executed prior to 2014 did not anticipate this situation and may contain broad language that could unintentionally result in the application of Medicaid standards to the non-Medicaid lines of business offered by the single legal entity. For example, if a state defines the entity subject to the contract through reference to something shared across lines of business, such as licensure as an insurer, both the Medicaid MCO and QHP could be subject to the terms of the contract with the state. To prevent ambiguity and overly broad restrictions, contracts should contain specific language to clearly define the state's intent that the contract is specific to the Medicaid plan being offered by the entity. This becomes critically important in the case of a single legal entity operating Medicaid and non-Medicaid lines of business. We strongly recommend that states and Medicaid health plans review their contracts to ensure that it clearly defines each party's rights and responsibilities.

As consumers may experience periodic transitions between Medicaid and QHP eligibility, and families may have members who are divided between Medicaid and QHP coverage, selecting a carrier that offers both types of products may be the most effective way for some consumers to manage their health care needs. Improving coordination of care and minimizing disruption to care is best achieved when the consumer has sufficient information about coverage options when making a plan selection. We believe that our proposed regulatory revisions would enable more complete and effective information sharing and consumer education while still upholding the intent of the Medicaid beneficiary protections detailed in the Act. Section 438.104 alone does not prohibit a managed care plan from providing information on a qualified health plan (QHP) to enrollees who could potentially enroll in a QHP as an alternative to the Medicaid plan due to a loss of eligibility or to potential enrollees who may consider the benefits of selecting an MCO, PIHP, PAHP, or PCCM that has a related QHP in the event of future eligibility changes. Our proposal would set minimum marketing standards that a state may build on as part of its contracts with entities providing Medicaid managed care.

Finally, we have also received inquiries about the use of social media outlets for dissemination of marketing information about Medicaid managed care. The definition of ''marketing'' in § 438.104 includes ''any communication from'' an entity that provides Medicaid managed care (including MCOs, PIHPs, PAHPs, etc.) and ''marketing materials'' include ''materials that . . . are produced in any medium.'' These definitions are sufficiently broad to include social media and we intend to interpret and apply § 438.104 as applicable to communication via social media and electronic means. To address these inquiries and to make this interpretation clear, we also propose to clarify the regulation text by adding unsolicited contact by email and texting as prohibited cold-call marketing activities in paragraph (b)(1)(v).

We believe these proposed revisions would clarify, for states and issuers, the scope of the marketing provisions in § 438.104, which generally are more detailed and restrictive than those imposed on QHPs under 45 CFR 156.225. While we continue to believe that the Medicaid managed care regulation correctly provides significant protections for Medicaid beneficiaries, we recognize that the increased prevalence in some markets of carriers offering both QHP and Medicaid products and seek to provide clearer and more targeted Medicaid managed care standards with our proposed changes.

b. Appeals and Grievances (§ 438.400, § 438.402, § 438,404, § 438.406, § 438.408, § 438.410, § 438.414, § 438.416, § 438.424, § 431.200, § 431.220 and § 431.244)

We propose several modifications to the current regulations governing the grievance and appeals system for Medicaid managed care to further align and increase uniformity between rules for Medicaid managed care and rules for

MA managed care plans and rules applicable to private health insurance and group health plans. The existing differences between the rules applicable to Medicaid managed care and those applicable to the MA and private insurance and group health plans concerning grievance and appeals processes inhibit the efficiencies that could be gained with a streamlined grievance and appeals process that applies across the market. A streamlined process would make navigating the appeals system more manageable for consumers in an increasingly fluid health care market. Our proposed changes in subpart F of part 438 would adopt new definitions, update appeal timeframes, and align certain processes for appeals and grievances. We also propose modifying §§ 431.200, 431.220 and 431.244 to effectuate the changes proposed to subpart F of part 438.

We are concerned that the different appeal and grievance processes for the respective programs and health coverage causes: (1) Confusion for beneficiaries who are transitioning between private health care coverage, MA coverage, and Medicaid managed care; and (2) inefficiencies for health insurance issuers that participate in both the public and commercial sectors. Aligning appeal and grievance procedures across these areas will provide consumers with a more manageable and consumer friendly appeals process and allow health insurers to adopt more consistent protocols across product lines.

The grievance, organization determination, and appeal regulations in 42 CFR part 422, subpart M, govern grievance, organization determinations, and appeals procedures for MA members. The internal claims and appeals, and external review processes for private insurance and group health plans are found in 45 CFR 147.136. We referred to both sets of standards in reviewing current Medicaid managed care regulations regarding appeals and grievances.

(1) Subpart F, Part 438

Two of our proposals concerning the grievance and appeals system for Medicaid managed care affect the entire subpart. First, we propose to add PAHPs to the types of entities subject to the standards of subpart F and propose to revise text throughout this subpart accordingly. Currently, subpart F only applies to MCOs and PIHPs. Unlike MCOs which provide comprehensive benefits, PIHPs and PAHPs provide a narrower benefit package. While PIHPs were included in the standards for a grievance system, PAHPs were excluded. In 2002 most PAHPs were, in actuality, capitated PCCM programs managed by individual physicians or small group practices and, therefore, should not be expected to have the administrative structure to support a grievance process. However, since then, PAHPs have evolved into arrangements under which entities—private companies or government subdivisions—manage a smaller subset of Medicaid covered services such as dental, behavioral health, and home and community-based services. Because some PAHPs may provide those medical services which typically are subject to medical management techniques such as prior authorization, we believe PAHPs should be expected to manage a grievance process, and therefore, propose that they be subject to the grievance and appeals standards of this subpart. In adding PAHPs to subpart F, our proposal would also change the current process under which enrollees in a PAHP may seek a State Fair Hearing (SFH) immediately following an action to deny, terminate, suspend, or reduce Medicaid covered services in favor of having the PAHP conduct the first level of review of such actions. We rely on our authority at sections 1902(a)(3) and 1902(a)(4) of the Act to propose extending these appeal and grievance provisions to PAHPs.

We note that some PAHPs receive a capitated payment to provide non-emergency medical transportation (NEMT) services to Medicaid beneficiaries; for these NEMT PAHPs, an internal grievance and appeal system does not seem appropriate. The reasons for requiring PAHPs that cover medical services to adhere to the grievance and appeals processes in this subpart are not present for a PAHP solely responsible for NEMT. We propose to distinguish NEMT PAHPs from PAHPs providing medical services covered under the state plan. Consequently, NEMT PAHPs will not be subject to these internal grievance and appeal standards. Beneficiaries receiving services from NEMT PAHPs will continue to have direct access to the SFH process to appeal adverse benefit determinations, as outlined in § 431.220. We request comment on this approach.

As a result of our proposal to have PAHPs generally follow the provisions of subpart F of part 438, we also propose corresponding amendments to §§ 431.220 and 431.244 regarding SFH, and changes to § 431.244 regarding hearing decisions. In § 431.220(a)(5), we propose to add PAHP enrollees to the list of enrollees that have access to a SFH after an appeal has been decided in a manner adverse to the enrollee; and in § 431.220(a)(6), we propose that beneficiaries receiving services from NEMT PAHPs will continue to have direct access to the SFH process. We propose no additional changes to § 431.220. In § 431.244, as in part 438 subpart F generally, in each instance where MCO or PIHP is referenced, we propose to add a reference to PAHPs.

Second, throughout subpart F, we propose to insert ''calendar'' before any reference to ''day'' to remove any ambiguity as to the duration of timeframes. This approach is consistent with the timeframes specified in regulations for the MA program at 42 CFR part 422, subpart M.

(2) Statutory Basis and Definitions (§ 438.400)

In general, the proposed changes for § 438.400 are to revise the definitions to provide greater clarity and to achieve alignment and uniformity for health care coverage offered through Medicaid managed care, private insurance and group health plans, and MA plans. We are not proposing to change the substance of the description of the authority and applicable statutes in § 438.400(a) but propose a more concise statement of the statutory authority.

In § 438.400(b), we propose a few changes to the defined terms. First, we propose to replace the term ''action'' with ''adverse benefit determination.'' The proposed definition for ''adverse benefit determination'' would include the existing definition of ''action'' and revisions to include determinations based on medical necessity, appropriateness, health care setting, or effectiveness of a covered benefit in revised paragraph (b)(1). We believe this would conform to the term used for private insurance and group health plans and lays the foundation for MCOs, PIHPs, or PAHPs to consolidate processes across Medicaid and private health care coverage sectors. We considered the term ''adverse determination'' but that is already used in § 431.202 to describe a nursing home level of care determination. Further, the term ''adverse benefit determination'' is used in 45 CFR 147.136 and 29 CFR. 2560.503–1, which are provisions governing internal grievance and appeals processes for private insurance (the group and individual insurance markets) and group health plans (fully-insured and self-insured plans). By adopting a uniform term for MCO, PIHP, or PAHP enrollees and enrollees in private insurance and group health plans, we hope consumers will be able to identify similar processes between lines of business, and be better able to navigate different health care coverage options more easily. Our proposal

would also update cross-references to other regulations affected by this proposed rule, delete the term ''Medicaid'' before the word ''enrollee,'' and consistently replace the term ''action'' in the current regulations in subpart F with the term ''adverse benefit determination'' throughout this subpart.

In addition to using the new term ''adverse benefit determination,'' we propose to revise the definition of ''appeal'' to add accuracy by stating that an appeal is a review by the MCO, PIHP, or PAHP, as opposed to the current definition which defines it as a request for a review. In the definition of ''grievance,'' we propose a conforming change to delete the reference to ''action,'' to delete the part of the existing definition that references the term being used to mean an overall system, and to add text to clarify the scope of grievances.

For clarity, we propose to separately define ''grievance system'' as the processes the MCO, PIHP, or PAHP implements to handle appeals and grievances and collect and track information about them. By proposing a definition for ''grievance system,'' we intend to clarify that a MCO, PIHP, or PAHP must have a formal structure of policies and procedures to appropriately address both appeals and grievances. We also propose to remove the reference to the state's fair hearing process from this definition as it is addressed in part 431, subpart E. This continued to be a significant source of confusion, even after the changes were made in the 2002 final rule, and we hope these proposed changes add clarity.

(3) General Requirements (§ 438.402)

We propose in paragraph (a) to add ''grievance'' in front of ''system'' and to delete existing language that defines a system in deference to the proposed new definition added in § 438.400. We also propose to add text to clarify that subpart F does not apply to NEMT PAHPs.

In paragraph (b), we propose to revise the paragraph heading to ''Level of appeals'' and limit MCOs, PIHP, and PAHPs to only one level of appeal for enrollees before beneficiaries exhaust the managed care plan's internal appeal process. Once this single level appeal process is exhausted, the enrollee would be able to request a SFH under subpart E of part 431. In conjunction with this proposal, we are also proposing to amend § 438.402(c)(1)(i) and § 438.408(f) with corresponding text that would have enrollees exhaust their MCO, PIHP, or PAHP appeal rights before seeking a SFH. Our proposal is designed to ensure that the MCO, PIHP, or PAHP process would not be unnecessarily extended by having more than one level of internal review. This proposal is consistent with the limit imposed on issuers of individual market insurance under 45 CFR 147.136(b)(3)(ii)(G) and MA organizations at § 422.578, although we acknowledge that issuers of group market insurance and group health plans are not similarly limited under 45 CFR 147.136(b)(2) and 29 CFR 2560.503–1(c)(3). We believe that this proposal would not impair the administrative alignment we seek in this context and ensures that enrollees can reach the SFH process within an appropriate time. We request comment on this proposal.

In paragraph (c)(1)(i), we propose to revise this section to permit an enrollee to request a SFH after receiving notice from the MCO, PIHP, or PAHP upholding the adverse benefit determination. We propose in paragraph (c)(1)(ii) to remove the standard for the enrollee's written consent for the provider to file an appeal on an enrollee's behalf. The current standard is not specified in section 1932(b)(4) of the Act and is inconsistent with similar MA standards for who may request an organization determination or a reconsideration at § 422.566(c)(1)(ii) and § 422.578, so we believe it is not necessary.

We propose in paragraph (c)(2) to delete the state's option to select a timeframe between 20 and 90 days for enrollees to file an appeal and propose to revise paragraphs (c)(2)(i) and (ii) to set the timing standards for filing grievances (at any time) and appeals (60 calendar days), respectively. For grievances, we do not believe that grievances need a filing limit as they do not progress to a SFH and thus do not need to be constrained by the coordination of timeframes. For appeals, proposed paragraph (c)(2)(ii) would permit an enrollee or provider to file an appeal within 60 calendar days of receipt of the notice of an adverse benefit determination. Medicare beneficiaries in a MA plan and enrollees in private health care coverage each have 60 calendar days to request an appeal under regulations governing MA plans (§ 422.582) and private insurance and group health plans (45 CFR 147.136(b)(2) and (b)(3) and 29 CFR 2560.503–1(h)(2)). By adjusting the timeframe for MCO, PIHP, or PAHP enrollees to file appeals to 60 calendar days from the date of notice of the adverse decision, our proposal would achieve alignment and uniformity across Medicaid managed care plans, MA organizations, and private insurance and group health plans, while ensuring adequate opportunity for beneficiaries to appeal. We note that the existing provisions of § 438.402 (b)(2)(i) are subsumed into the proposed paragraph (c)(1)(i) and (ii) while the existing provisions of paragraph (b)(2)(ii) would be deleted consistent with our proposal in § 438.408(f)(1) concerning exhaustion of the MCO's, PIHP's, or PAHP's appeal process.

In paragraph (c)(3), we propose to add headings to paragraphs (c)(3)(i) and (c)(3)(ii) and to make non-substantive changes to the text setting forth the procedures by which grievances or appeals are filed. Under our proposal, as under current law, a standard grievance or appeal may be requested orally or in writing (which includes online), and standard appeal requests made orally must be followed up in writing. Expedited appeal requests may be requested either way, and if done orally, the consumer does not need to follow up in writing.

We request comment on the extent to which states and managed care plans are currently using or plan to implement an online system that can be accessed by enrollees for filing and/or status updates of grievances and appeals. If such systems are not in use or in development, we request comment on the issues influencing the decision not to implement such a system and whether an online system for tracking the status of grievances and appeals should be required at the managed care plan level.

(4) Timely and Adequate Notice of Adverse Benefit Determination (§ 438.404)

In § 438.404, we propose to revise the section heading to a more accurate and descriptive title, ''Timely and adequate notice of adverse benefit determination.'' In paragraph (a), we propose a non-substantive wording revision to more accurately reflect the intent that notices must be timely and meet the information standards detailed in proposed § 438.10.

In paragraph (b), describing the minimum content of the notice, we propose to delete paragraph (b)(4) (about the state option for exhaustion) to correspond to our proposal in § 438.408(f) and redesignate the remaining paragraphs accordingly. In paragraph (b)(2), we propose to clarify that the reason for the adverse benefit determination includes the right of the enrollee to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the enrollee's claim for benefits. This

additional documentation would include information regarding medical necessity criteria, and any processes, strategies, or evidentiary standards used in setting coverage limits. In new paragraph (b)(5), we propose to replace expedited ''resolution'' with expedited ''appeal process'' to add consistency with wording throughout this subpart. We further propose to add the phrase ''consistent with State policy'' in paragraph (b)(6) to be consistent with a proposed change in § 438.420(d) regarding the MCO's, PIHP's, or PAHP's ability to recoup from the enrollee under a final adverse decision be addressed in the contract and that such practices be consistent across both FFS and managed care delivery systems within the state. While notice of the possibility of recoupment under a final adverse decision is an important beneficiary protection, we recognize that such notice may deter an enrollee from exercising the right to appeal. We would issue guidance following publication of the rule regarding the model language and content of such notice to avoid dissuading enrollees from pursuing appeals.

In paragraph (c), we propose to revise paragraph (c)(4) to replace ''extends the timeframe in accordance with . . .'' with ''meets the criteria set forth . . .'' to more clearly state that MCOs, PIHPs, and PAHPs cannot extend the timeframes without meeting the specific standards of § 438.210(d)(1)(ii). Lastly, in paragraph (c)(6), we propose to update the cross reference from § 438.210(d) to § 438.210(d)(2).

(5) Handling of Grievances and Appeals (§ 438.406)

In addition to language consistent with our overall proposal to make PAHPs subject to the grievance and appeals standards for MCOs and PIHPs, we are proposing to reorganize § 438.406 to be simpler and easier to follow and to revise certain procedural standards for appeals. Existing paragraph (a) is revised by adding the existing provision in paragraph (a)(1) to paragraph (a), which specifies that each MCO, PIHP, and PAHP must give enrollees any reasonable assistance, including auxiliary aids and services upon request, in completing forms and taking other procedural steps.

In paragraph (b), we propose to revise the paragraph heading and redesignate existing provisions in paragraphs (a)(2) and (a)(3) as (b)(1) and (b)(2), respectively; we also propose to add grievances to the provisions of both. MCOs, PIHPs, or PAHPs would have to send an acknowledgment receipt for each appeal and grievance and follow the limitations on individuals making decisions on grievances and appeals in paragraphs (b)(2)(i) and (ii). In new (b)(2)(i), we propose to add that individuals who are subordinates of individuals involved in any previous level of review are, like the individuals who were involved in any previous level of review, excluded from making decisions on the grievance or appeal. This proposed revision adds another level of beneficiary protection that we believe is appropriate and is consistent with standards under the commercial rules in 45 CFR 147.136 that incorporate 29 CFR 2560.503–1(h)(3)(ii). Redesignated paragraph (b)(2)(ii) remains unchanged from its current form. Consistent with the standards under the commercial rules in 45 CFR 147.136 that incorporate 29 CFR 2560.503–1(h)(2)(iv), we propose to add a new paragraph (b)(2)(iii) to specify that individuals that make decisions on appeals and grievances take all comments, documents, records, and other information submitted by the enrollee into account regardless of whether the information had been considered in the initial review. We propose to redesignate current paragraph (b)(2) as (b)(4) and add ''testimony'' in addition to evidence and legal and factual arguments. We also propose to use the phrase ''legal and factual arguments'' to replace the phrase ''allegations of fact or law'' in the current text for greater clarity.

We note that, currently, in paragraph (b)(3) the enrollee must have the opportunity before and during the appeal process to examine the case file, medical record and any documents or records considered during the appeal process. We propose to redesignate this paragraph as paragraph (b)(5) and to replace ''before and during'' with ''sufficiently in advance'' of resolution, to add specificity. We also propose to add ''new or additional evidence'' to the list including case file, medical records, and any other documents or records that must be available to the enrollee. This language in paragraph (b)(5) would align with the disclosure standards applicable to private insurance and group health plans in 45 CFR 147.136(b)(2)(ii)(C)(1). Existing paragraph (b)(4) would be redesignated as paragraph (b)(6) without change.

(6) Resolution and Notification: Grievances and Appeals (§ 438.408 and § 431.244(f))

We propose to make significant modifications to § 438.408 to further align Medicaid managed care standards with MA and private insurance and group health plan standards. We are proposing several significant modifications as explained in more detail below: (1) Changes in the timeframes to decide appeals and expedited appeals, (2) strengthen notice standards for extensions, and (3) change the processes for receiving a SFH for enrollees of MCOs, PIHPs, and PAHPs. In addition, we propose to reorganize the regulation for greater clarity and to add the phrase ''consistent with state policy'' to paragraph (e)(2)(iii) to be consistent with our proposal in § 438.420(d).

In § 438.408(b)(2), we propose to adjust the timeframes in which MCOs, PIHPs, and PAHPs would have to make a decision about an enrollee appeal to align with the standards applicable to a MA organization. Currently, MCOs and PIHPs may have up to 45 days to make a decision about a standard (non-expedited) appeal. In § 422.564(e), MA plans must make a decision about first level appeals in 30 days, while Part D plans must provide a decision in 7 days under § 423.590(a)(1). Federal regulations on the commercial insurance market permit up to 60 days for a standard decision on an internal appeal (see § 147.136(b)(2)(i) and (b)(3), incorporating 29 CFR 2560.503–1(b)(1) for individual health insurance issuers and group health insurance issuers and plans). We are proposing to shorten the timeframe for MCO, PIHP, and PAHP appeal decisions from 45 days to 30 calendar days, which would achieve alignment with MA standards while still allowing adequate time for decision-making and response.

In paragraph (b)(3), we propose to adjust the Medicaid managed care timeframes for expedited appeals to align with standards applicable to MA and the commercial insurance market. Currently under subpart F, MCOs and PIHPs have 3 working days from receipt of a request to make a decision in an expedited review. The MA (§ 422.572(a)) and commercial insurance regulations (29 CFR 2590.715–2719(c)(2)(xiii)) stipulate that a health plan must make a decision within 72 hours of receiving a request for expedited review. We propose to modify our expedited appeal decision timeframes from 3 working days to 72 hours. The change would improve the speed with which enrollees would receive a MCO, PIHP, or PAHP decision on critical issues, and align Medicaid managed care with Medicare and private insurance and group health plans. Again, this change would enable insurance companies that operate multiple product lines to have consistent regulatory standards governing its operations.

We also propose to strengthen the notification responsibilities on the MCO, PIHP, or PAHP following an extension of the timeframe for resolution of a grievance or appeal, when the extension is not requested by the enrollee. In addition, we propose to add existing text from paragraph (c)(2)(i) regarding timeframe extensions that are not requested by the enrollee to paragraph (c)(2). We also propose to add a standard for the MCO, PIHP, or PAHP to make reasonable efforts to give the enrollee prompt oral notice of the delay in paragraph (c)(2)(i). We propose to add the current standards in § 438.404(c)(4)(i) and (ii) to § 438.408(c)(ii) and (iii), which describe the standards on the MCO, PIHP, or PAHP for an extension of the timeframe for standard or expedited appeals for clarity and consistency.

In § 438.408(d)(1) and (2), we propose to add a provision requiring that grievance notices (as established by the state) and appeal notices (as directed in the regulation) from a MCO, PIHP, or PAHP ensure meaningful access for people with disabilities and people with limited English proficiency by, at a minimum, meeting the standards described at § 438.10.

In § 438.408(e), we propose to add ''consistent with state policy'' in paragraph (e)(2)(iii). This is added here to be consistent with a proposed change in § 438.420(d) which stipulates that the MCO's, PIHP's, or PAHP's ability to recoup from the enrollee under a final adverse decision must be addressed in the contract and that such practices be consistent across both FFS and managed care delivery systems within the state. For example, if the state does not exercise the authority for recoupment under § 431.230(b) for FFS, the same practice must be followed by the state's contracted MCOs, PIHPs, and PAHPs.

In § 438.408(f), we are proposing to modify the Medicaid managed care appeals process such that an enrollee must exhaust the MCO, PIHP, or PAHP appeal process prior to requesting a SFH. This would eliminate a bifurcated appeals process while aligning with Medicare and the private market regulations. Under current Medicaid rules, states have the discretion to decide if enrollees must complete the MCO, PIHP, or PAHP appeal process before requesting a SFH or whether they can request a SFH while the MCO, PIHP, or PAHP appeal process is still underway. Depending on the state's decision in this regard, this discretion has led to duplicate efforts by the MCO, PIHP, or PAHP and the state to address an enrollee's appeal. Both MA rules and regulations governing private insurance and group health plans have a member complete the health plan's internal appeal process before seeking a second—that is, external—level review. Our proposed change would be consistent with both those processes.

Specifically, under the proposed change in paragraph (f)(1), a MCO, PIHP, or PAHP enrollee would have to complete the MCO, PIHP, or PAHP appeal process before requesting a SFH. Maintaining two processes at the same time can be confusing and cumbersome to all parties involved. With the proposed change, consumers would still be able to take advantage of the SFH process, but in a consecutive manner which would lead to less confusion and effort on the enrollee's part. Moreover, our proposed reduction in the timeframes that a MCO, PIHP, or PAHP would have to take action on an appeal (from 45 to 30 calendar days) in § 438.408(b)(2) would permit enrollees to reach the SFH process more quickly. Further, a federal standard would eliminate variations across the country and lead to administrative efficiencies at the MCO, PIHP, and PAHP level. We believe that our proposal achieves the appropriate balance between alignment, beneficiary protections, and administrative simplicity. For consistency, this change is also reflected in proposed revisions to § 438.402(b) and § 438.404(b)(4) as noted previously.

We propose in new paragraph (f)(2) to revise the timeframe enrollees have to request a SFH to align with filing timeframes applicable to group health plans and private insurance. Currently in § 438.408(f)(1), a state may set the timeframe for an enrollee to request a SFH within the range of 20 to 90 days from the date of notice of the MCO's, PIHP's, or PAHP's resolution. By adjusting the timeframe for enrollees to file SFH requests to 120 calendar days, we give enrollees more time to gather the necessary information, seek assistance for the SFH process and make the request for a SFH.

We also propose a number of changes to § 431.244, Hearing Decisions, that correspond to these proposed amendments to § 438.408. In § 431.244, we propose to remove paragraph (f)(1)(ii) which references direct access to a SFH when permitted by the state. As that option is proposed to be deleted in § 438.408(f)(1), it should also be deleted in § 431.244(f)(1). In § 431.244(f)(2), we considered whether to modify the 3 working day timeframe on the State to conduct an expedited SFH. In the interest of alignment, we examined the independent and external review timeframes in both MA and QHPs and found no analogous standard or consistency for final administrative action regarding expedited hearings. We believe that SFHs are different than a review by an Independent Review Organization (IRO) or Independent Review Entity (IRE). We have therefore decided to keep the SFH expedited timeframe at 3 working days. We propose to delete current paragraph (f)(3) as it is no longer relevant given the deletion of direct access to SFH proposed revision to § 438.408(f)(1). We propose no additional changes to § 431.244.

(7) Expedited Resolution of Appeals (§ 438.410)

In addition to the revisions to add PAHPs to the scope of this regulation, we propose to revise § 438.410(c)(2) to replace the current general language on oral and written notification with a cross reference to § 438.408(c)(2), which as proposed, provides more specificity on the responsibilities of the MCO, PIHP, or PAHP when extending timeframes for resolution. We also propose a grammatical correction to paragraph (b) to replace the word ''neither'' with ''not.'' We propose no other changes to this section.

(8) Information About the Grievance System to Providers and Subcontractors (§ 438.414)

In addition to the change proposed throughout this subpart in connection with PAHPs, we propose to update the cross reference from § 438.10(g)(1) to § 438.10(g)(2)(xi) to be consistent with our proposed revisions to § 438.10, discussed in more detail below in section I.B.6.d.

(9) Recordkeeping Requirements (§ 438.416)

In § 438.416, we propose to modify the recordkeeping standards under subpart F to achieve consistency across states by specifying the recordkeeping elements. The current recordkeeping provisions do not set standards for the type of appeals and grievance information to be collected, and only stipulate that states must review that information as part of an overall quality strategy. The proposed recordkeeping language here would set minimum standards for the types of information that must be collected to create consistency across states. Under the proposed updates to the recordkeeping section, states would have to review information about appeals and grievances as part of its ongoing monitoring, which would allow for better tracking of issues and promote faster interventions.

Specifically, we propose to redesignate the existing provisions of § 438.416 as a new paragraph (a), adding that the state must review the information as part of its monitoring of managed care programs and to update and revise its comprehensive quality strategy. We are proposing to add a new paragraph (b) to specifically list the information that must be contained in the record of each grievance and appeal: A description of the reason for the appeal or grievance, the date received, the date of each review or review meeting if applicable, the resolution at each level, the date of resolution, and the name of the enrollee involved. Finally, we are proposing to add a new paragraph (c) to stipulate that the record be accurately maintained and made accessible to the state and available to CMS upon request.

(10) Effectuation of Reversed Appeal Resolutions (§ 438.424)

In addition to adding PAHPs to § 438.424 as discussed earlier in this preamble, we propose to revise the current rule in paragraph (a) so that the MCO, PIHP, or PAHP must effectuate a reversal of an adverse benefit determination and authorize or provide such services no later than 72 hours from the date it receives notice of the adverse benefit determination being overturned. This is consistent with the timeframes for reversals by MA organizations and independent review entities in the MA program, as specified in § 422.619 for expedited reconsidered determinations, when the reversal is by the MA organization or the independent review entity. In addition to providing consistency across these different managed care programs, and the increases in efficiency that we predict as a result of this alignment, we believe that 72 hours is sufficient time for an MCO, PIHP, or PAHP to authorize or provide services that an enrollee has successfully demonstrated are covered services. We solicit comment on this proposal and on our assumptions as to the amount of time that is necessary for an MCO, PIHP, or PAHP to authorize or provide services.

c. Medical Loss Ratio (§ 438.4, § 438.5, § 438.8, and § 438.74)

The Affordable Care Act includes standards for a minimum medical loss ratio (MLR) in the private health insurance and MA markets. A standardized MLR calculation allows regulators the ability to conduct a retrospective analysis of premiums paid compared to overall expenditures to ensure a fair and equitable arrangement is maintained; additionally, the outcomes of the MLR calculation may be considered by issuers and managed care plans in future rate development or decision making. We believe that MLR calculation and reporting are important tools to ensure that capitation rates set for Medicaid managed care programs are actuarially sound and adequately based on reasonable expenditures on covered medical services for enrollees.

As of 2015, Medicaid and CHIP are the only health benefit coverage programs to not utilize a minimum MLR for managed care plans. We understand some states require a minimum MLR or some similar calculation, but these standards vary widely depending on state defined characteristics and have differing levels of enforcement. In keeping with our goals of alignment with the health insurance market whenever reasonable and appropriate and to ensure that capitation rates are actuarially sound, we propose that the MLR for MCOs, PIHPs, and PAHPs be calculated, reported, and used in the development of actuarially sound capitation rates. Under sections 1903(m)(2) and regulations based on our authority under section 1902(a)(4) of the Act, actuarially sound capitation rates must be utilized for MCOs, PIHPs, and PAHPs; actuarial soundness requires that capitation payments cover reasonable, appropriate and attainable costs in providing covered services to enrollees in Medicaid managed care programs. Medical loss ratios are one tool that could be used to assess whether capitation rates are appropriately set by generally illustrating how those funds are spent on claims and quality improvement activities as compared to administrative expenses, demonstrating that adequate amounts under the capitation payments are spent on services for enrollees. In addition, MLR calculation and reporting would result in responsible fiscal stewardship of total Medicaid expenditures by ensuring that states have sufficient information to understand how the capitation payments made for enrollees in managed care programs are expended.

A national standard for Medicaid managed care plans that aligns with the methodologies for health insurance issuers found in 45 CFR 158 *et seq.* and the rules for MA and Part D plans found in § 422.2400 *et seq.* and § 423.2400 *et seq.* would provide the most consistent approach to calculating and reporting MLR. A consistent methodology across multiple markets (private, Medicare, and Medicaid) would allow for administrative efficiency for the states in their roles regulating insurance and Medicaid and for issuers and managed care entities to collect and measure data necessary to calculate an MLR and provide reports. In addition, a consistent standard would allow comparison of MLR outcomes consistently from state to state and among commercial, Medicare, and Medicaid managed care plans.

To establish the standard that MLR be calculated, reported and used in the Medicaid managed care rate setting context, we propose to incorporate these standards in the actuarial soundness standards proposed in § 438.4 and § 438.5, and to add new § 438.8 and § 438.74, which would establish, respectively, the substantive standards for how MLR is calculated and reported by MCOs, PIHPs, and PAHPs and state responsibilities in oversight of the MLR standards.

(1) Medical Loss Ratio as a Component of Actuarial Soundness (§ 438.4 and § 438.5)

First, we propose standards for how MLR calculations and reporting must be considered in both a prospective and retrospective manner in the rate setting process to ensure that capitation rates are actuarially sound.

In § 438.4(b)(8), we propose that rates for MCOs, PIHPs, and PAHPs must be set such that, using the projected revenues and costs for the rate year, the MCO, PIHP, or PAHP would achieve an MLR of at least 85 percent, but not exceed a reasonable maximum threshold that would account for reasonable administrative costs. We believe that 85 percent is the appropriate minimum threshold and is the industry standard for MA and large employers in the private health insurance market. We believe that considering the MLR as part of the rate setting process would be an effective mechanism to ensure that program dollars are being spent on health care services, covered benefits, and quality improvement efforts rather than on potentially unnecessary administrative activities. Additionally, our proposed use of the MLR and 85 percent threshold is very similar to the use of the MLR in the proposed and final rules entitled ''Rate Increase Disclosure and Review'' (75 FR 81012 and 76 FR 29973) that implemented 45 CFR 154.205 for that provision considers whether a rate increase that would be subject to CMS' Center for Consumer Information and Insurance Oversight's (CCIIO) review would result in a projected MLR below the 85 percent MLR standard. In addition, as issuers may participate in multiple product lines, we believe that there would be administrative efficiencies from using consistent

standards and methods for calculating MLR. We also believe that issuers, states, and CMS would benefit from an MLR that can be compared to other similar measures.

We also believe that it is appropriate to consider the MLR in rate setting to protect against the potential for an extremely high MLR (for example, an MLR greater than 100 percent). When an MLR is too high, it means there is a possibility that the capitation rates were set too low. Capitation rates that are too low raise concerns about enrollees' access to services, the quality of care, provider participation, and the continued viability of the Medicaid managed care plans in that market. Additionally, extremely high MLRs may indicate that the capitation rates do not account for reasonable administrative costs, which could result in poor client and provider experiences. We are hesitant to set a specific upper bound for the MLR that represents a maximum upper threshold that is analogous to 85 percent as a minimum threshold. States are better positioned to establish and justify a maximum MLR threshold, which accounts for the type of services being delivered, the state's administrative requirements, the maturity of the program and the managed care plans. Nonetheless, states should consider an appropriate maximum threshold to ensure that the capitation rates are adequate for necessary and reasonable administrative costs and we have proposed such a standard, rather than a specific percentage, for an upper bound on MLR experience.

In § 438.5(b)(5), we propose that states must use the annual MLR calculation and reporting from MCOs, PIHPs, or PAHPs as part of developing rates for future years. While the projected MLR measurement proposed in § 438.4(b)(8) appears to be most closely tied to the actuarial soundness of the rates, we believe that knowing the actual MLR experienced by an MCO, PIHP, or PAHP each year will provide important information necessary for rate setting for future years. We propose that states must take the information about past MLR experience into account as part of the rate setting process. If an MCO, PIHP, or PAHP has not met the 85 percent MLR in prior years, the state would use that information in the development of future capitation rates. If the MCO's, PIHP's, or PAHP's reported MLR calculation continues to reflect that the actual experience varies from those projections used in the rate development process, the state, and its actuary, would use that information during the development of the capitation rates for future rating periods. The information and process, in turn, assist in setting a rate where the MCO, PIHP, or PAHP would reasonably be expected to achieve at least an 85 percent MLR in future contract years.

(2) Standards for Calculating and Reporting Medical Loss Ratio (§ 438.8)

Second, we propose minimum standards for how the MLR must be calculated and the associated reports submitted to the state so that the MLR information used in the rate setting process is available and consistent. Our goal in developing the MLR standards is to be as consistent as possible with the NAIC model and the regulations on health insurers in the private market and MA, while taking into consideration the unique aspects of delivering services through Medicaid managed care. While we considered both the commercial market and MA standards when developing this proposed rule, we more closely aligned with the commercial rules as we believe the need for consistency is greater between plans on the Marketplace and in Medicaid. We did incorporate MA standards for the calculation of the MLR when we believed the needs of incorporating standards of a public program outweighed our desire to create efficiency between the calculations from the Marketplace to Medicaid.

In paragraph (a), we propose that states ensure through their contracts with any risk based MCO, PIHP, or PAHP that starts on or after January 1, 2017, the MCO, PIHP, or PAHP would meet the standards proposed in § 438.8. Non-risk PIHP or PAHP contracts by their nature do not need to calculate a MLR standard since contractors are paid an amount equal to their incurred service costs plus an amount for administrative activities. Through this proposed paragraph, we propose that MLR reporting years would start with contracts beginning on or after January 1, 2017. We believe that most states use 1 year contract periods with MCOs, PIHPs, and PAHPs, but for those states that do not, we propose that the state have its MCOs, PIHPs, and PAHPs calculate and report the MLR for the rating period beginning in 2017. This means if a state has a contract running from October 2017 through September 2018 and the state wishes to align their MLR reporting year with the contract year, the first MLR reporting year would be October 2017 through September 2018. We believe that starting the MLR calculation and reporting standards with contract years starting in 2017 will allow enough time for states, MCOs, PIHPs, and PAHPs to take any necessary measures to prepare for application of the MLR after this proposed rule is finalized. We request comment on this timeframe and whether we should consider a start date that is some specific time after the final rule becomes effective.

Paragraph (b) proposes to define terms used in this proposed section, including the terms MLR reporting year and non-claims cost; several terms that are relevant for purposes of credibility adjustments are also proposed but are discussed with proposed § 438.8(h). We discuss the definition of non-claims cost below in connection with the proposal at § 438.5(d)(2)(v)(A) and how such costs are excluded from incurred claims. The private market and MA both calculate the MLR on a calendar year basis. While we expect some states to use a calendar year as the basis for the calculation of the MLR, other states may choose to use a different time period. States vary their contract years and we propose to give states the option of aligning their MLR reporting year with the contract year if they so choose so long as the MLR reporting year is the same as the rating period, although states will not be permitted to have a MLR reporting year that is more than 12 months. We considered allowing an MLR calculation consistent with any rating period even if the rating period was more than 12 months, but were concerned that allowing varying lengths of time in the MLR reporting year could create inconsistencies with how the credibility factors are applied to the MLR calculation. In addition, the 12 month period is consistent with how the commercial and MA MLR is calculated. In the event the state changes the time period, for example, transitions from paying capitation rates on a state fiscal year to a calendar year, the state could choose if the MLR calculation would be done for two 12 month periods with some period of overlap. Whichever methodology the state elects, the state will need to clarify the decision in the actuarial certification and take this overlap into account when determining the penalties or remittances (if any) on the MCO, PIHP, or PAHP for not meeting the standards developed by the state.

Proposed paragraph (c) addresses certain minimum standards for the use of an MLR if a state elects to mandate a minimum MLR for an MCO, PIHP, or PAHP. We know that some states have imposed MLR percentages on certain plans that equal or exceed 85 percent and we do not want to prevent states from continuing those practices if they believe a higher MLR percentage is appropriate. Therefore, our proposed

regulation permits each state, through its law, regulation, or contract with the MCO, PIHP, or PAHP to establish a minimum MLR that may be higher than 85 percent, although the method of calculating the MLR would still be consistent with the standards in proposed § 438.8. The parameters on state flexibility, to set an MLR requirement that is no lower than 85 percent but that is calculated consistent with the requirements in proposed § 438.8, are based on our authority under section 1902(a)(4) of the Act and recognizes that for some managed care programs, for example, MLTSS programs, states may find it appropriate to establish an MLR standard that is higher than 85 percent. If a state were to set an MLR standard below 85 percent that was calculated in a different manner than the proposals in § 438.8, it would be inconsistent with our approach of assuming an MLR of at least 85 percent in the development of actuarially sound capitation rates, as described in § 438.4(b)(7). We understand that some states use their existing MLR standard as a general rule or guidepost for health plan evaluation as opposed to recouping funds from the MCO, PIHP, or PAHP if its MLR falls below the state-define threshold. While states would not have to collect remittances from the MCOs, PIHPs, or PAHPs through this proposed rule (see discussion of § 438.8(j)), we strongly encourage states to implement the types of financial contract provisions that would drive MCO, PIHP, and PAHP performance in accordance with the MLR standard. In section I.B.1.c.(3) of this proposed rule, we address the treatment of any federal share of potential remittances.

Proposed paragraphs (d), (e) and (f) propose the basic methodology and components that make up the calculation of the MLR. The calculation of the MLR proposed for Medicaid managed care is the sum of the MCO's, PIHP's, or PAHP's incurred claims, expenditures on activities that improve health care quality, and activities specified under proposed § 438.608(a)(1) through (5), (7), (8) and (b) (subject to the cap in § 438.8(e)(4)), divided by the adjusted premium revenue collected, taking into consideration any adjustments for MCO, PIHP, or PAHP enrollment (known as a credibility adjustment). Our proposal uses the same general calculation as the one established in 45 CFR 158.221 (private plan MLR) with proposed differences as to what is included in the numerator and the denominator to account for differences in the Medicaid program. The proposal also calculates the MLR over a 12-month period rather than a 3-year period.

The total amount of the numerator is proposed in paragraph (e) which, as noted above, is equal to the sum of the incurred claims, expenditures on activities that improve health care quality, and, subject to the cap in paragraph (e)(4), activities related to proposed standards in § 438.608(a)(1) through (5), (7), (8) and (b) of this proposed rule. As proposed, there are certain amounts that would need to be included or deducted from incurred claims for this MLR calculation. Generally, the proposed definition of incurred claims comports with the private market and MA standards, with Medicaid differing in several ways, such as:

- We propose that amounts the MCO, PIHP, or PAHP receives from the state for purposes of stop-loss payments, risk-corridor payments, or retrospective risk adjustment are deducted from incurred claims. MCOs, PIHPs, and PAHPs should not include those payments as incurred claims (proposed § 438.8(e)(2)(ii)(C) and (e)(2)(iv)(A)).
- Likewise, if a MCO, PIHP, or PAHP must make payments to the state because of a risk-corridor or risk adjustment calculation, this proposed rule would include those amounts in incurred claims (proposed § 438.8(e)(2)(iv)(A)).
- A state may operate Medicaid-specific solvency funds for its managed care program. If MCOs, PIHPs, or PAHPs must pay into those funds, this proposed rule would consider those payments incurred claims (proposed § 438.8(e)(2)(iii)(A)).
- Due to proposed changes in subpart H, we believe there is a possibility that the adjustment to claims in the MLR numerator of Medicaid MCOs, PIHPs, or PAHPs could have fewer recoveries from fraudulent or excluded providers because of enhanced fraud prevention and monitoring measures. We want to encourage Medicaid MCOs, PIHPs, and PAHPs to build and sustain a program integrity infrastructure that has strong prevention activities as well as robust processes for the detection, referral and recovery of improper payments, including potential fraud, waste and abuse. Therefore, we propose that expenditures related to fraud prevention activities, as set forth in § 438.608(a)(1) through (5), (7), (8) and (b), may be attributed to the numerator but would be limited to 0.5 percent of MCO's, PIHP's, or PAHP's premium revenues. Section I.B.4.c.(4) of this proposed rule provides a discussion of the proposed revisions to § 438.608. We also propose to make clear in the regulatory text that the expenses for fraud prevention activities described in § 438.8(e)(4) would not duplicate expenses for fraud reduction efforts for purposes of accounting for recoveries in the numerator pursuant to § 438.8(e)(2)(iii)(C), and the same would be true in the converse. While many employees of a managed care plan may conduct activities that support fraud, waste, and abuse prevention through the normal course of duties, the expenditures related to the proposed fraud, waste, and abuse activities attributable to the numerator, as proposed in § 438.8(e)(4), are associated with the work of employees that directly carry out those functions and associated data analytics and technological infrastructure to conduct these ongoing fraud prevention activities. Successful technology and analytics to conduct fraud, waste, and abuse prevention and detection will have some of the following characteristics: A process for incorporating field intelligence, policy knowledge and clinical expertise (or other expertise relevant to the industry) into the development of the predictive or other sophisticated algorithms to ensure that the results are actionable; a method for tracking, measuring, and evaluating the actions taken based on the information produced, and the presence of an analytical environment for data exploration that includes the historic information necessary for predictive modeling and an operational environment that quickly displays results and visualization (graphics, maps) that assists the end user in taking action.

We believe that this proposed limit on expenditures for fraud prevention is a reasonable amount to encourage MCOs, PIHPs, and PAHPs to build and maintain robust and dynamic fraud prevention programs. In addition, we assert that the 0.5 percent figure is appropriate as a limitation because fraud prevention and monitoring costs should not yield a one-to-one ratio relative to recoveries due to fraud, waste, or abuse. In other words, one dollar spent on fraud prevention and monitoring activities should render more than one dollar in recoveries. We request comment on the approach to incorporating fraud prevention activities and the proportion of such expenditures in the numerator for the MLR calculation, as this proposal is unique to Medicaid managed care. We also request general comments on the proposal, as well as other methodologies. Specifically, we request comment on alternative options that only account for

increased investments in fraud prevention activities relative to prior-year levels, so as to prevent incorporation in the numerator of fraud prevention activities plans currently undertake.

Non-claims costs would be considered the same in Medicaid as they are in the commercial market and MA rules. We propose in § 438.8(e)(2)(v)(A)(3) that certain amounts paid to a health care professional are not included as incurred claims; we intend to use the illustrative list in the similar provisions at § 422.2420(b)(4)(i)(C) and § 158.140(b)(3)(iii) to interpret and administer this aspect of our proposal. Incurred claims would not include non-claims costs and remittances paid to the state from a previous year's MLR experience. In paragraph (e)(2)(iii)(A), we propose that payments made by an MCO, PIHP, or PAHP to mandated solvency funds must be included as incurred claims, which is consistent with the commercial market regulations on market stabilization funds at 45 CFR 158.140(b)(2)(i). Paragraph (e)(2)(iv) would take a consistent approach with the commercial rules at 45 CFR 158.140(b)(4)(ii) that amounts that must either be included in or deducted from incurred claims are net payments related to risk adjustment and risk corridor programs. We propose in paragraph (e)(2)(v) that the following non-claims costs are excluded from incurred claims: Amounts paid to third party vendors for secondary network savings, network development, administrative fees, claims processing, and utilization management; and amounts paid for professional or administrative services. This approach is consistent with the expenditures that must be excluded from incurred claims under the commercial rules at 45 CFR 158.140(b)(3). Proposed paragraph (e)(2)(vi) would incorporate the provision in MA regulations at 42 CFR 422.2420(b)(5) for the reporting of incurred claims for a MCO, PIHP, or PAHP that is later assumed by another entity to avoid duplicative reporting in instances where one MCO, PIHP, or PAHP is assumed by another.

Through these proposed rules in § 438.8(e)(3), an activity that improves health care quality can be included in the numerator as long as it meets one of three standards: (1) It meets the definition in 45 CFR 158.150(b) (the private insurance market MLR rule) of an activity that improves health care quality and is not excluded under 45 CFR 158.150(c); (2) it is an activity specific to Medicaid managed care External Quality Review activities (described in subpart E); or (3) it is an activity related to Health Information Technology and meaningful use, as defined in 45 CFR 158.151 and excluding any costs that are deducted or excluded from incurred claims under paragraph (e)(2). Regarding activities related to Health Information Technology and meaningful use, we encourage states to support the adoption of certified technology that enables interoperability across providers and supports seamless care coordination for enrollees. In addition, we refer MCOs, PIHPs, and PAHPs to the Office of the National Coordinator for Health Information Technology's draft of the ''2015 Interoperability Standards Advisory'' published for public comment (available at *http://www.healthit.gov/standards-advisory*), which proposes a set of best available standards and implementation specifications enabling priority health information exchange use cases.

We understand that some managed care plans cover more complex populations in their Medicaid line of business than in their commercial line of business; therefore, the case management/care coordination standards are more intensive and costly for Medicaid health plans than in a typical private market group health plan. Consistent with the use of the term in the private market, we believe the definition of activities that improve health care quality in 45 CFR 158.150 is broad enough to encompass MCO, PIHP, and PAHP activities related to service coordination, case management, and activities supporting state goals for community integration of individuals with more complex needs such as individuals using LTSS. For that reason, we are not specifically identifying these activities separately in this rule, but expect MCOs, PIHPs, and PAHPs would include the cost of appropriate outreach, engagement, and service coordination in this category. We request comment on this approach.

Paragraph (f) proposes what would be included in the denominator for calculation of the MLR. Generally, the denominator is the MCO's, PIHP's, or PAHP's premium revenue less any expenditure for federal or state taxes and licensing or regulatory fees. In proposed § 438.8(f)(2), we specify what must be included in premium revenue. We expect that a state will have adjusted capitation payments appropriately for every population enrolled in the MCO, PIHP, or PAHP so that the capitated payment reasonably reflects the costs of providing the services covered under the contract for those populations and meets the actuarial soundness standards in § 438.4 through § 438.7. Additionally, because many states make payments to MCOs, PIHPs, or PAHPs for one-time, specific life events of enrollees—events that do not receive separate payments in the private market or MA—these payments need to be included as premium revenue in the denominator. Typical examples of these are maternity ''kick-payments'' where a payment to the MCO is made at the time of delivery for to offset the costs of prenatal, postnatal and labor and delivery costs for an enrollee.

As proposed in paragraph (f)(3), we would treat taxes, licensing and regulatory fees in the same way as they are treated in the private market and MA; they would be deducted from premium revenue. Similar to the private market in 45 CFR 158.161(b), fines or penalties imposed on the MCO, PIHP, or PAHP would not be deducted from premium revenue and must be considered non-claims costs (proposed § 438.8(e)(2)(v)(A)(*4*)). Consistent with MA, we propose in paragraph (f)(3)(v) to allow Community Benefit Expenditures (CBEs), as defined in 45 CFR 158.162(c) (which is analogous to the definition in § 422.2420(c)(2)(iv)(A)), to be deducted up to the greater of 3 percent of earned premiums or the highest premium tax rate in the applicable state multiplied by the earned premium for the MCO, PIHP, or PAHP. We request comment on this proposal. Paragraph (f)(4) incorporates the provision for MLR under MA regulations at § 422.2420(c)(4) for the reporting of the denominator for a MCO, PIHP, or PAHP that is later assumed by another entity to avoid duplicative reporting in instances where one MCO, PIHP, or PAHP is assumed by another.

Paragraph (g) proposes our standards for allocation of expenses. MCOs, PIHPs, and PAHPs would use a generally accepted accounting method to allocate expenses to only one category, or if they are associated with multiple categories, pro-rate the amounts so the expenses are only counted once.

Section 2718(c) of the Public Health Service Act charges the National Association of Insurance Commissioners (NAIC) with developing uniform methodologies for calculating measures of the expenditures that make up the MLR calculation, and provides that ''such methodologies must be designed to take into account the special circumstances of small plans, different types of plans, and newer plans.'' To address the special circumstances of smaller plans, the NAIC model regulation allows smaller plans to adjust their MLR calculations by applying a

''credibility adjustment.'' In paragraph (h), we propose to adopt this method of credibility adjustment for MCOs, PIHPs, and PAHPs. To the extent possible, we propose to follow the approach used in both the private market (45 CFR 158.230) and MA and Medicare Part D MLR rules (§§ 422.2440, 423.2440).

A credibility adjustment is a method to address the impact of claims variability on the experience of smaller plans due to random statistical variation and we propose to define a credibility adjustment in this manner in § 438.8(b). All issuers experience some random claims variability, where actual claims experience deviates from expected claims experience. In a health plan with a large number of enrollees the impact of such random deviations is less than in plans with fewer enrollees. One source of variability is the impact of large claims, which are infrequent but have a greater impact on financial experience than average or typical claims. Large claims have a disproportionate impact on small plans because the higher claim cost is spread across a smaller premium base. These random variations in the claims experience for enrollees in a smaller plan may cause an issuer's reported MLR to be below or above a particular standard in any particular year, even though the state or the issuer estimated in good faith that the combination of the projected premiums and claims would produce an MLR that meets the specific standard. It is important to emphasize that health insurance rates are the product of assumptions, estimates, and projections. For example, when an actuary projects that the rate he or she has calculated will produce an 85 percent MLR, whether in fact it will produce an 85 percent MLR, depends on whether the assumptions the actuary has made—such as those concerning the characteristics and health status of the enrollees covered by the plan, the intensity and frequency with which its enrollees will use health care services, and unit costs—turn out to be correct. All things being equal, it is more likely that those assumptions will turn out to be correct when an issuer insures a large number of enrollees rather than a small number, and differences between the assumptions and actual experience would likewise be smaller when an issuer covers a larger number of enrollees.

After extensive analysis and public discussion, the NAIC adopted a credibility adjustment table designed to result in an issuer that charges premiums intended to produce an 80 percent MLR to pay a rebate less than 25 percent of the time. We propose to adopt this approach of less than 25 percent in paragraph (h)(4)(ii). Toward the conclusion of its public proceedings on these issues, the NAIC gave some consideration to setting the base credibility factors so that such an issuer would have to pay a rebate less than 10 percent of the time. The credibility factors in that case would have been roughly twice as large as the factors the NAIC adopted. The case made in favor of making this change is that it would reduce the likelihood of requiring a plan to pay a rebate simply because of chance variation in claims experience. However, it would also have increased the likelihood that a plan setting premiums to achieve an MLR that is less than the applicable MLR standard would avoid paying a rebate, and it would have reduced the size of the rebates that plans pricing below the MLR standard would have to pay. The NAIC concluded that the credibility factors it adopted more equitably balance the consumers' interest in requiring plans that should pay rebates to pay rebates against the issuers' interest in minimizing the risk of paying rebates as a result of chance variations.

We propose to adopt a credibility adjustment methodology in paragraph (h)(4). The NAIC recommends that the credibility factors be monitored and reevaluated in light of developing experience as the Affordable Care Act reforms are implemented over the next several years. We concur with this recommendation and we intend both to monitor the effects of the credibility adjustment and, as appropriate, to update the credibility adjustment method within the parameters of the methodology proposed in this rule.

The NAIC developed a standard for the minimum number of life-years for the plan's MLR to be determined at least partially credible. The NAIC selected the standard in part to avoid having credibility adjustments that would exceed 10 percent (credibility adjustments are described later in this section). The standards for the private market and MA and Part D were selected using similar criteria. We propose in paragraph (h)(4)(iii) setting the minimum number of member months (that is, the sum of the number of months that each individual was enrolled in the plan over the period that the MLR is measured) to determine at least partial credibility such that the maximum credibility adjustment is equal to or less than 10 percent. Using member months would be consistent with the approach taken for MA and Part D, and we believe the use of member months is more consistent with Medicaid data and reports. We would also recommend that states that collect remittances from plans based on the MLR, would not collect remittances from any plan that is determined to be non-credible on the basis of the number of member months of enrollment in the plan.

In paragraph (h)(4)(iv), we propose to follow the NAIC's assumption that variations of less than approximately 1 percent are reasonably to be expected based on ordinary variation in claims experience of very large plans. We propose to consider the experience of such plans to be fully credible, and would recommend that such a plan should have to pay a remittance based on its reported MLR, to the extent that a state chooses to collect a remittance as described in paragraph (j) of this section.

The NAIC designated a minimum number of life-years that would be needed to assign full credibility to a plan's MLR and a minimum number of life-years that would be needed to assign at least partial credibility to a plan's MLR. For the MLR of plans that are assigned partial but not full credibility, the NAIC developed a credibility adjustment to apply to the MLR. We propose to adopt a similar approach based on the variability of Medicaid expenditures in paragraph (h)(4)(v). For purposes of the credibility adjustment for Medicaid MCOs, PIHPs, and PAHPs we use the term ''member months'', and propose to define the term in § 438.8(b) as the ''number of months an enrollee or group of enrollees is covered by an MCO, PIHP, or PAHP over a specified time period, such as a year.''

The Office of the Actuary modeled the distribution of the MLR using the following statistical formula by applying the Central Limit Theorem:

$$MLR_n = \frac{\sum_{i=1}^{n} X_i}{n\mu/0.85} \xrightarrow{d} N\left(0.85, \frac{0.85^2\sigma^2}{n\mu^2}\right)$$

Where:

X_i is the annual claim amount with mean (μ) and variance (σ^2) for an individual. X_i is assumed to be independently and identically distributed for each individual.

n is the number of individuals in the group; and

$$N\left(0.85, \frac{0.85^2\sigma^2}{n\mu^2}\right) \text{ denotes the Normal distribution with mean, } 0.85, \text{ and variance, } \frac{0.85^2\sigma^2}{n\mu^2}.$$

The numerator of the formula represents the aggregate claims (a variable), and the denominator represents the aggregate premium. The denominator is modeled as a single point equal to the expected premium because we are not evaluating the variability in the denominator.

The credibility adjustment equals the expected value of the MLR less the 25th percentile (25 percent target failure rate). This difference can be calculated by multiplying the *z*-score for the standard normal distribution by the standard deviation for the MLR. The credibility adjustment equals:

$$\left|-0.6745\frac{0.85\sigma}{\sqrt{n}\mu}\right|$$

Where –0.6745 is the *z*-score for the 25th percentile of the standard normal distribution.

We propose that, in addition to calculating the number of member-months needed to determine the minimum number of member-months for a MLR to be partially credible and for a MLR to be fully credible, the credibility adjustment would also be determined at several other numbers of member-months in between those levels and published. For a MLR that is determined to be partially credible, the credibility adjustment would be calculated by interpolating between the credibility adjustments at the nearest member-month levels published. For example, if a MLR for a plan with 5,000 member-months would receive a credibility adjustment of 2.0 percent and a plan with 10,000 member-months would receive a credibility adjustment of 1.0 percent, then we would determine that a plan with 6,000 member-months would receive a credibility adjustment of 1.8 percent using linear interpolation, as demonstrated in the equation below:

$$1\% + [(10{,}000 - 6{,}000)/(10{,}000 - 5{,}000)] \times (2\% - 1\%) = 1.8\%$$

More generally:

$$Credibility\ Adjustment = CA_b + \left[\left.(MM_b - MM)\right/(MM_b - MM_a)\right] \times (CA_a - CA_b)$$

Where *MM* is the number of member-months for a specific plan for which the MLR is measured; CA_a and CA_b are the credibility adjustments for the published member-month levels below and above the number of member-months *MM* for a specific plan; and MM_a and MM_b are the member-month levels below and above the number of member-months *MM* for a specific plan (for which the credibility adjustments would be CA_a and CA_b).

As proposed in § 438.8(h)(4)(vi), the number of member-months required for full and partial credibility for the MLR may be rounded for the purposes of administrative simplicity. We believe the standards would be clearer and easier to implement if they were rounded rather than unrounded. We intend that, under our proposal, we would round the member-month standards to the nearest 1,000, but depending on the results of the calculations of the number of member-months we may choose a different degree of rounding to ensure that the credibility thresholds are consistent with the objectives of this regulation.

In paragraph (i)(1), the minimum MLR would be calculated and reported for the entire population enrolled in the MCO, PIHP, or PAHP under the contract with the state unless the state directs otherwise. We expect that most states would have the MCO, PIHP, or PAHP calculate the MLR on a contract-wide basis, but we propose to permit flexibility for states that may choose to separate the MLR calculation by Medicaid eligibility group based on differences driven by the federal medical assistance percentage (FMAP) (to simplify accounting with the federal government), by capitation rates, or for legislative tracking purposes. However, while states could divide eligibility groups for MLR calculation purposes, states may not apply different standards of review or different MLR minimums to different eligibility groups. The state may choose any aggregation method described, but proposed paragraph (k)(1)(xii) stipulates that the MCO, PIHP, and PAHP must clearly show in their report to the state which method it used.

Paragraph (j) proposes that an MCO, PIHP, or PAHP pay a remittance to the state if the state elects to impose a remittance standard on a MCO, PIHP,or PAHP that does not meet the minimum MLR standard set by the state as described in proposed in § 438.8(c). We strongly encourage states to incent MCO, PIHP, and PAHP performance consistent with their authority under state law.

We propose that MCOs, PIHPs, and PAHPs would submit a report meeting specific content standards and in the time and manner established by the state (so long as the deadline is within 12 months of the end of the MLR reporting year). We believe this will be

enough time after the end of the MLR reporting year for the state to reconcile any incentive or withhold arrangements they have with the MCOs, PIHPs, and PAHPs and for the managed care plans to calculate the MLR accurately. The specified contents of the report in paragraph (k) are considered the minimum information necessary for the state to monitor and confirm compliance with the standards for the calculation of the MLR as specified in this section. We request comment on whether this is an appropriate timeframe.

Because there is always some uncertainty when health plans enter a new market, we propose in paragraph (l) that MCOs, PIHPs, and PAHPs need not calculate or report their MLR in the first year they contract with the state to provide Medicaid services if the state chooses to exclude that MCO, PIHP, or PAHP from the MLR calculation in that year. If the state chose that option, the first MLR reporting year the MCO, PIHP, or PAHP would be the next MLR reporting year and only the experience of the MCO, PIHP, or PAHP for that MLR reporting year would be included. We considered whether to provide similar flexibility for situations where a Medicaid MCO, PIHP, or PAHP covers a new population (that is, the state decides to cover a new population of Medicaid beneficiaries in managed care). While we agree it is possible that there may be unknown risk to the plans for new populations, we do not believe any additional considerations need to be factored in for these cases because capitation payments and any risk mitigation strategy employed by the state would already be considered in the numerator and denominator. Moreover, if we were to allow those newly added populations to be carved out of the MLR calculation, we would create an unnecessary misalignment between Medicaid and the rules governing the private market and MA MLR. We request comment on this proposal and whether we should further define when a health plan newly contracts with the state.

We anticipate that states may make retroactive changes to capitation rates that could affect the MLR calculation for a given MLR reporting year. Permissible retroactive adjustments to the final capitation rate are discussed in section I.B.3.e. of this proposed rule. We propose in paragraph (m) that in any case where a state makes a retroactive adjustment to the rates that affect a MLR calculation for a reporting year, the MCO, PIHP, or PAHP would need to recalculate the MLR and provide a new report with the updated figures.

In paragraph (n) we propose that the MCO, PIHP, or PAHP provide an attestation when submitting the report specified under proposed paragraph (k) that gives an assurance that the MLR was calculated in accordance with the standards in this proposed section.

(3) State Requirements (§ 438.74)

We propose minimum standards for state oversight of the MLR standards in § 438.74. Specifically, we propose two key standards related to oversight for states when implementing the MLR for contracted MCOs, PIHPs, and PAHPs: (1) Report to CMS a summary description of the outcomes of the MLR calculations for each MLR reporting year; and (2) re-pay the federal share of any remittances the state chooses to collect from the MCOs, PIHPs, or PAHPs. The proposed report in paragraph (a) is a summary description of the MLR calculations for each of the MCOs, PIHPs, and PAHPs in the state, and must be included with the rate certification that would be submitted under § 438.7 of this proposed rule. In proposed paragraph (b), if the state chooses to collect any remittances from the MCOs, PIHPs, or PAHPs for not meeting the minimum MLR standard, then the state would also need to determine a methodology for how the state will return the federal share of that remittance. With much of the Medicaid expansion population included in managed care and the possibility of the FMAP changing within the MLR reporting year, a MLR calculated on a contract basis may have varying levels of federal match within the MLR remittance. If a state has decided not to segregate MLR reporting by population, the state will need to submit to CMS the methodology of how the federal share of the remittance was calculated that would be reviewed and approved in the normal CMS–64 claiming protocol.

2. Standard Contract Provisions (§ 438.3, § 438.6)

Our existing regulations at § 438.6 stipulate that MCO, PIHP, and PAHP capitation rates must be set on an actuarially sound basis, based on section 1903(m)(2)(A)(iii) of the Act (for MCOs) and section 1902(a)(4) of the Act (for PIHPs and PAHPs). Section 438.6 currently also includes standards related to contracting and contract terms for MCOs, PIHPs, and PAHPs. Based on our experience with the changing Medicaid managed care environment, we are proposing several updates to these standards for contract terms and actuarial soundness. In addition, the current language also includes provisions that are better organized by specific topic. To that end, we propose to restructure the standards currently codified in § 438.6 at the same time as we propose several substantive changes in these areas. Our proposal would divide the content into the following five new sections, four of which specifically address setting actuarially sound capitation rates.

- § 438.3—Standard Contract Provisions
- § 438.4—Actuarial Soundness
- § 438.5—Rate Development Standards
- § 438.6—Special Contract Provisions Related to Payment
- § 438.7—Rate Certification Submission

We discuss in section I.B.3., the substance of our proposal concerning setting actuarially sound capitation rates, and focus in this section I.B.2. on our proposal for the standard contract provisions for MCO, PIHP, and PAHP contracts. Where we propose to reorganize or recodify existing provisions into new sections, they are so noted in this preamble discussion. Likewise, where we have proposed additional specificity, those are clearly delineated. We welcome comments on both the approach and content of this portion of the proposed rule.

We propose to add a new § 438.3 to contain the standard provisions for MCO, PIHP, and PAHP contracts that are distinguishable from the rate setting process. As proposed, these provisions generally set forth specific elements that states must include as performance standards in their managed care contracts. As published in 2002, § 438.6 contained contract standards from part 434 that were carried over from that section and updated as necessary when part 438 was created to contain all standards for Medicaid managed care programs, including the standards for actuarially sound capitation payments and for risk-sharing and related payment mechanisms. To improve the clarity and readability of part 438, we propose that § 438.3 would include the standard contract provisions from current § 438.6 that are unrelated to payment. We recognize that additional contract standards that direct aspects of the MCO's, PIHP's, or PAHP's operations appear elsewhere in this part; however, to preserve the continuity of and familiarity with part 438 over the past decade, we do not believe it is necessary or appropriate to completely consolidate all contract standards into one section.

We are proposing that the provisions currently codified in § 438.6 as paragraphs (a) through (m) be redesignated respectively as § 438.3(a)

through (l), (p) and (q), with some revisions as described below. These proposed paragraphs address standards for our review and approval of contracts, entities eligible for comprehensive risk contracts, payment, prohibition of enrollment discrimination, services covered under the contract, compliance with applicable laws and conflict of interest safeguards, provider-preventable conditions, inspection and audit of financial records, physician incentive plans, advance directives, subcontracts, choice of health care professional, additional rules for contracts with PCCMs, and special rules for certain HIOs.

First, in § 438.3(a) related to our review and approval of contracts, we propose to add the regulatory flexibility for us to set forth procedural rules—namely timeframes and detailed processes for the submission of contracts for review and approval—in sub-regulatory materials, and add a new standard for states seeking contract approval prior to a specific effective date that proposed final contracts must be submitted to us for review no later than 90 days before the planned effective date of the contract. Under our proposal, the same timeframe standard would also apply to rate certifications, as proposed § 438.7(a) incorporates the review and approval process of § 438.3(a). To the extent that the final contract submission is complete and satisfactory responses to questions are exchanged in a timely manner, we believe that 90 days is a reasonable and appropriate timeframe for us to conduct the necessary level of review of these documents to verify compliance with federal standards and thereby authorize FFP concurrent with the health plan's initiation of performance under the contract. We acknowledge a state's interest in receiving approval prior to the planned effective date and propose that states provide us with adequate time to conduct our review to ensure compliance with applicable rules. In addition, for purposes of consistency throughout part 438, we are removing specific references to the CMS Regional Offices and replacing it with a general reference to CMS. This proposed change does not represent a modification in the role of the Regional Offices.

We propose for § 438.3(b) and (d) to merely redesignate the existing provisions at § 438.6(b) and (d), with the addition of PCCM entities to paragraph (d) consistent with our proposal discussed in section I.B.6.e. of this proposed rule about PCCM entities. Wherever there is a reference to PCCM in existing regulatory text being moved or amended as part of our proposal for § 438.3, we propose to add PCCM entities.

In proposed § 438.3(c), we propose to restate our longstanding standard currently in § 438.6(c)(2)(ii) that the final capitation rates for each MCO, PIHP, or PAHP must be specifically identified in the applicable contract submitted for our review and approval. We also propose to clarify in this paragraph that the final capitation rates must be based only upon services covered under the state plan and that the capitation rates represent a payment amount that is adequate to allow the MCO, PIHP, or PAHP to efficiently deliver covered services in a manner compliant with contractual standards.[3]

We propose to redesignate the provisions prohibiting enrollment discrimination currently at § 438.6(d) as new § 438.3(d) and propose to replace the reference to the Regional Administrator with CMS for consistency with other proposals to refer uniformly to CMS in the regulation text. We also propose to add sex as a protected category as discussed in the proposed changes in § 438.3(f) below.

The current regulation at § 438.6(e) addresses the services that may be covered by the MCO, PIHP, or PAHP contract. We propose to move that provision to § 438.3(e). The existing provision also prohibits services that are in addition to those in the Medicaid state plan from being included in the capitation rate and we have proposed to address that standard in proposed § 438.3(c) above.

We also propose to redesignate the existing standard for compliance with applicable laws and conflict of interest standards from existing § 438.6(f) to § 438.3(f)(1) with the addition of a reference to section 1557 of the Affordable Care Act, which prohibits discrimination in health programs that receive federal financial assistance. Similarly, we propose to add sex as a protected category for purposes of MCO, PIHP, PAHP, or PCCM enrollment practices in the enrollment provisions proposed to be moved to § 438.3(d)(4). We also propose a new standard, at proposed § 438.3(f)(2), to state more clearly the existing standard that all contracts comply with conflict of interest safeguards (described in § 438.58) and section 1902(a)(4)(C) of the Act.

We propose to redesignate the standards related to provider reporting of provider-preventable conditions currently codified in § 438.6(f)(2)(i) to the new § 438.3(g). With this redesignation, we propose to limit these standards to MCOs, PIHPs, and PAHPs, because those are the entities for which these standards are applicable.

We propose to move the inspection and audit rights for the state and federal government from § 438.6(g) to new § 438.3(h) and to expand the existing standard to include access to the premises, physical facilities and equipment of contractors and subcontractors where Medicaid-related activities or work is conducted. In addition, we propose to clarify that the State, CMS, and the Office of the Inspector General may conduct such inspections or audits at any time.

As part of our proposal to redesignate the provisions related to physician incentive plans from § 438.6(h) to new § 438.3(i), we propose to correct the outdated references to Medicare+Choice organizations to MA organizations. We propose to redesignate the provisions for advance directives currently in § 438.6(i) as § 438.3(j). We propose to redesignate the provisions for subcontracts currently at § 438.6(l) as § 438.3(k) and also propose to add a cross-reference to § 438.230 that specifies standards for subcontractors and delegation. We propose to redesignate the standards for choice of health care professional currently at § 438.6(m) at § 438.3(l).

In proposed § 438.3(m), we propose to add a new standard that MCOs, PIHPs, and PAHPs submit audited financial reports annually. We believe this standard is appropriate and necessary for these managed care plans because such information is a source of base data that must be used for rate setting purposes in proposed § 438.5(c). We propose that the audits are conducted in accordance with generally accepted accounting principles and generally accepted auditing standards. We propose to reserve § 438.3(n).

In proposed § 438.3(o), we propose that contracts covering long-term services and supports provide that services that could be authorized through a waiver under section 1915(c) of the Act or a state plan amendment through section 1915(i) or 1915(k) be delivered consistent with the settings standards in § 441.301(c)(4).

We propose to redesignate existing § 438.6(j) (special rules for certain HIOs) and (k) (additional rules for contracts

[3] We note that in ''Medicaid and Children's Health Insurance Programs; Mental Health Parity and Addiction Equity Act of 2008; the Application of Mental Health Parity Requirements to Coverage Offered by Medicaid Managed Care,'' published April 10, 2015 [CMS–2333–P], we proposed that certain additional costs could also be used to develop capitation rates. We anticipate that if that proposal is finalized, that provision would be codified as part of § 438.6(e) and redesignated through this proposed rule as § 438.3(e)).

with PCCMs) as § 438.3(p) and (q). As part of our proposed redesignation of the HIO-specific provisions from existing § 438.6(j) to new § 438.3(p), we also propose to correct a cross-reference in that paragraph. The existing language cross-references § 438.6(a) to determine whether certain HIOs may enter into risk contracts. This cross-reference first appeared in the 1998 proposed rule when § 438.6(a) contained the contract review standards for risk-bearing entities. In the final rule for part 438, those standards were moved to § 438.6(b) and the reference in § 438.6(j) was not updated. We propose to correct that oversight by using a cross reference to paragraph (a) of this proposed section, where we have proposed to designate the contract review standard. We propose to redesignate the additional contract standards specific to PCCM contracts from existing § 438.6(k) to new § 438.3(q) so that all contract standards for MCOs, PIHPs, and PAHPs are separated from any special rules for PCCMs. We believe this restructuring adds clarity to our rules.

In proposed § 438.3(r), we propose to set standards for contracts with PCCM entities, in addition to those standards specified for PCCM contracts in proposed § 438.3(q), including the submission of such contracts for our review and approval to ensure compliance with § 438.10 (information standards). If the PCCM entity contract provides for shared savings, incentive payments or other financial reward for improved quality outcomes, § 438.330 (performance measurement), §§ 438.340 (managed care elements of comprehensive quality strategy), and 438.350 (external quality review) would be applicable.

In proposed § 438.3(s), we propose to add standards for contracts with MCOs, PIHPs, or PAHPs that are contractually obligated to provide coverage of covered outpatient drugs. The proposed MCO standards are based primarily on section 1903(m)(2)(A)(xiii) of the Act and we rely on our authority under section 1902(a)(4) to extend them to PIHPs and PAHPs that are contractually obligated to provide covered outpatient drugs. In addition, we rely on section 1902(a)(4) of the Act to address, for all managed care plans within the scope of this proposal, requirements that are outside the scope of section 1903(m)(2)(A)(xiii) of the Act, namely the proposal at § 438.3(s)(1), (4) and (6).

Section 2501(c)(1)(C) of the Affordable Care Act amended section 1903(m)(2)(A) of the Act to add clause (xiii) to add certain standards applicable to contracts with MCOs. In the February 2, 2012 **Federal Register**, we published the ''Medicaid Program; Covered Outpatient Drugs'' proposed rule that included the addition of a definition for covered outpatient drugs in § 447.502 (77 FR 5318). We propose here to incorporate appropriate definitions related to covered outpatient drugs in part 438 should such definitions be implemented and have used the phrase ''as defined in section 1927(k)'' in our proposed regulation text as a placeholder for that in § 438.3(s).

In paragraph (s)(1), we propose that the MCO, PIHP, or PAHP must provide coverage of covered outpatient drugs (as defined in section 1927(k)(2) of the Act) as specified in the contract and in a manner that meets the standards for coverage of such drugs imposed by section 1927 of the Act as if such standards applied directly to the MCO, PIHP, or PAHP. This is intended to clarify that when the MCO, PIHP, or PAHP provides prescription drug coverage, the coverage of such drugs must meet the standards set forth in the definition of covered outpatient drugs at section 1927(k)(2) of the Act. The MCO, PIHP, or PAHP may be permitted to maintain its own formularies for covered outpatient drugs that are under the contract, but when there is a medical need for a covered outpatient drug that is not included in their formulary but that is within the scope of the contract, the MCO, PIHP, or PAHP must cover the covered outpatient drug under a prior authorization process. This proposal is based on our authority under section 1902(a)(4) of the Act to mandate methods of administration that are necessary for the efficient operation of the state plan. Furthermore, if an MCO, PIHP, or PAHP is not contractually obligated to provide coverage of a particular covered outpatient drug, or class of drugs, the state is required to provide the covered outpatient drug through FFS in a manner that is consistent with the standards set forth in its state plan and the requirements in section 1927 of the Act.

In paragraph (s)(2), we propose to implement section 1903(m)(2)(A)(xiii)(III), specifically, we propose that MCOs, PIHPs, and PAHPs report drug utilization data necessary for the state to bill for rebates under section 1927(b)(1)(A) to the state within 45 calendar days after the end of each quarterly rebate period to ensure that MCO, PIHP, or PAHP data is included with the FFS invoicing of manufacturers for rebates for the state in the same rebate period. Such utilization information must include, at a minimum, information on the total number of units of each dosage form and strength and package size by National Drug Code of each covered outpatient drug dispensed or covered by the MCO, PIHP, or PAHP.

As amended, section 1927(b)(1)(A) of the Act provides in part that states must bill manufacturers for rebates for drugs dispensed to enrollees with a Medicaid managed care plan and the proposed standard in paragraph (s)(2) will help facilitate state compliance with the statutory directive. In paragraph (s)(3), we propose that the MCO, PIHP, or PAHP must have procedures in place to exclude utilization data for drugs subject to discounts under the 340B Drug Pricing Program from the utilization reports submitted under proposed paragraph (s)(2). Section 2501(c) of the Affordable Care Act modified section 1927(j)(1) of the Act to specify that covered outpatient drugs are not subject to the rebate standards if such drugs are both subject to discounts under section 340B of the PHS Act and dispensed by MCOs. Section 340B of the PHS Act prohibits covered entities from billing Medicaid for covered outpatient drugs purchased at discounted 340B prices if the drugs are subject to a Medicaid rebate. Section 1903(m)(2)(A)(xiii)(III) of the Act provides that the reporting standard for MCOs does not include information about drugs that are not subject to the rebates under section 1927 of the Act. As we propose in paragraph (s)(2), that MCOs, PIHPs, and PAHPs must report utilization data, it would follow that covered outpatient drugs purchased at 340B prices need to be excluded from the utilization reports to the state to avoid duplicate discounts for rebates paid by manufacturers. To ensure that drug manufacturers will not be billed for rebates for drugs purchased and dispensed under the 340B Drug Pricing Program, MCOs, PIHPs, or PAHPs must have mechanisms in place to identify these drugs and exclude the reporting of this utilization data to the state as to avoid the manufacturer from incurring a duplicate discount on these products.

In paragraph (s)(4), we propose that MCOs, PIHPs, or PAHPs that provide coverage of covered outpatient drugs also operate a drug utilization review (DUR) program that is consistent with the standards in section 1927(g) of the Act; this standard means that the DUR program operated by the MCO, PIHP, or PAHP would be compliant with section 1927(g) of the Act if it were operated by the state in fulfilling its obligations under section 1927 of the Act. This does not mean that the DUR program operated by the MCO, PIHP, or PAHP must be the same as that operated by the state, but that the MCO's, PIHP's, or

PAHP's DUR program meets the requirements in section 1927(g) of the Act. This proposal is based on our authority under section 1902(a)(4) of the Act. We recognize that MCOs, PIHPs, and PAHPs that are contractually responsible for covered outpatient drugs generally conduct utilization review activities as these activities promote the delivery of quality care in a cost effective and programmatically responsible manner. We believe that because the MCO, PIHP, or PAHP is providing coverage for covered outpatient drugs as part of the state plan instead of the state providing that coverage through FFS, it is appropriate to extend the DUR responsibilities associated with such coverage to the MCO, PIHP, or PAHP. Section 1927(g)(1)(A) of the Act provides, in part, that states must provide a DUR program for covered outpatient drugs to assure that prescriptions: (1) Are appropriate; (2) are medically necessary; and (3) are not likely to result in adverse medical results. We intend that our proposal in paragraph (s)(4) be met when the DUR program operated by an MCO, PIHP, or PAHP meets these standards. We recommend that the state's DUR Board coordinate with the MCOs, PIHPs, and PAHPs to coordinate review activities. In paragraph (s)(5), we propose that the MCO, PIHP, or PAHP would have to provide a detailed description of its DUR program activities to the state on an annual basis. The purpose of the report is to ensure that the parameters of section 1927(g) of the Act are being met by the MCO's, PIHP's, or PAHP's DUR program, as proposed under paragraph (s)(4).

Finally, in paragraph (s)(6), we propose that the state stipulate that the MCO, PIHP, or PAHP conduct the prior authorization process for covered outpatient drugs in accordance with section 1927(d)(5); we rely again on our authority under section 1902(a)(4) of the Act for this proposal. We believe that because the MCO, PIHP, or PAHP is providing coverage for covered outpatient drugs as part of the state plan instead of the state providing that coverage through FFS, it is appropriate to extend the prior authorization standards associated with such coverage to the MCO, PIHP, or PAHP. Therefore, we propose that the MCO, PIHP, or PAHP would provide a response to a request for prior authorization for a covered outpatient drug by telephone or other telecommunication device within 24 hours of the request and dispense a 72 hour supply of a covered outpatient drug in an emergency situation. We request comment on the proposals for MCO, PIHP, or PAHP coverage of covered outpatient drugs.

In proposed § 438.3(t), we propose a new contract provision for MCO, PIHP, or PAHP contracts that cover Medicare-Medicaid dually eligible enrollees and delegate the state's responsibility for coordination of benefits to the health plan. Under our proposal, in states that use the automated crossover process for FFS claims, the contract would need to provide that the MCO, PIHP, or PAHP sign a Coordination of Benefits Agreement and participate in the automated crossover process administered by Medicare. In FFS, states are responsible for dually eligible beneficiaries' Medicare cost-sharing and use Medicare's automated crossover process to reduce burden on providers. Under this crossover process, a Medicare provider—who may not be part of the managed care plan's network—submits a claim to Medicare and there is an automatic crossover to the state for whatever Medicaid payment would be due. As more MCOs, PIHPs, or PAHPs plans are contractually responsible for Medicare deductibles and co-insurance, providers face a much more complex set of processes. If an MCO, PIHP, or PAHP does not enter into a Coordination of Benefits Agreement with Medicare, providers may have to submit separate bills in electronic or paper format. Each health plan has its own process, and often, a single provider may have patients in two or three different health plans. Contract provisions requiring an MCO, PIHP, or PAHP serving dually eligible enrollees to enter into a Coordination of Benefits Agreement with Medicare and participate in automated crossover would encourage providers to serve dually eligible beneficiaries. Further, such a standard would also reduce administrative burden for the relevant entities, ensuring more efficient provision of benefits to enrollees.

We propose to add a new paragraph (u) to permit MCOs and PIHPs to receive a capitation payment from the state for an enrollee aged 21 to 64 that spends a portion of the month for which the capitation is made as a patient in an institution for mental disease (IMD) so long as the facility is a hospital providing psychiatric or substance use disorder (SUD) inpatient care or sub-acute facility providing psychiatric or SUD crisis residential services and the stay in the IMD is for less than 15 days in that month. As background, paragraph (B) following section 1905(a)(29) provides that federal financial participation is not available for any medical assistance under title XIX for services provided to an individual ages 21 to 64 who is a patient in an IMD facility. Under this broad exclusion, no FFP is available for the cost of services provided either inside or outside the IMD while the individual is a patient in the facility. In light of the flexibility that managed care plans have had historically to furnish care in alternate settings that meet an enrollee's needs, we propose to clarify that managed care plans have had flexibility under risk contracts to provide alternative services or services in alternative settings in lieu of covered services or settings if cost-effective, on an optional basis, and to the extent the managed care plan and the enrollee agree that such setting or service would provide medically appropriate care.

We aim to propose rules on substitute providers under Medicaid managed care programs for CMS's ''in lieu of'' policy in particular. For reasons set forth later in this section, we believe that addressing managed care plan flexibility in the context of short inpatient or sub-acute IMD stays is necessary because of what we believe are access issues for short-term inpatient psychiatric and SUD treatment. We propose to include sub-acute facilities in our proposal as an option to address access issues for inpatient services. Our proposed clarification of policy aims to ensure that the use of IMD settings in lieu of covered settings for this care is sufficiently limited so as to not contravene the Medicaid coverage exclusion in section 1905(a)(29)(B) of the Act. Our proposal recognizes that managed care plans have flexibility in ensuring access and availability of covered services while ensuring that use of an appropriate alternate setting does not endanger beneficiaries' overall access to Medicaid benefits for the entire month during which a brief stay occurs. We welcome comment on these proposals, as well as other recommendations for addressing the IMD payment exclusion in managed care delivery systems.

Managed care programs may achieve efficiency and economic savings compared to Medicaid FFS programs by managing care through numerous means, including networks of providers, care coordination and case management. We have previously acknowledged such increased efficiencies and savings, *see* 67 FR 41005, and current § 438.6(e) (proposed to be redesignated as § 438.3(e)) permit managed care plans to provide additional services not covered in the state plan, but such services cannot be included when determining payment rates. We believe that to implement the IMD exclusion in the managed care plan context by

prohibiting or limiting the payment through the capitation rate for services when an enrollee is a patient in an IMD is contrary to the flexibilities managed care plans have had in the delivery of services. We could take a narrow view of section 1905(a)(29)(B) of the Act and prohibit the payment, either entirely or in part, of the capitation rate for any month during which a beneficiary is a patient in any IMD for any part of the month, or to require mid-month changes in capitation payments and enrollment status. Either of these alternatives would have the potential to disrupt the coordination and management of care for such beneficiaries that managed care plans otherwise use. We also acknowledge that inherent in transferring the risk for Medicaid coverage during a period means that capitation payments may be made for months during which no Medicaid services are used by a particular beneficiary who is enrolled with the plan. Thus, we believe that it is appropriate to permit states to make a monthly capitation payment that covers the risk of services that are eligible for FFP rendered during that month when the enrollee is not a patient in an IMD, even though the enrollee may also be a patient in an IMD during a portion of that same period. A corollary of our proposal is that capitation payments may not be made if the specified conditions outlined in this section are not met and that a state would have to ensure that covered Medicaid services are provided on a FFS basis or make other arrangements to assure compliance. We seek comment on our proposed approach to providing this flexibility under managed care and alternative permissible options under the statute.

We clarify here that services rendered to a patient in an IMD may be considered ''in lieu of services'' covered under the state plan, as described in this proposed rule. ''In lieu of services'' are alternative services or services in a setting that are not included in the state plan or otherwise covered by the contract but are medically appropriate, cost effective substitutes for state plan services included within the contract (for example, a service provided in an ambulatory surgical center or sub-acute care facilities, rather than an inpatient hospital). However, an MCO, PIHP or PAHP may not require an enrollee to use an ''in lieu of'' arrangement as a substitute for a state plan covered service or setting, but may offer and cover such services or settings as a means of ensuring that appropriate care is provided in a cost efficient manner. Accordingly, the contract may not explicitly require the MCO or PIHP to use IMD facilities, and must make clear that the managed care plan may not make the enrollee receive services at an IMD facility versus the setting covered under state plan. However, the contract could include, in its list of Medicaid-covered services to be provided under the contract, services such as inpatient psychiatric hospital services. The MCO or PIHP could then purchase these services from an IMD rather than an inpatient hospital if it so chooses in order to make the covered services available. This is consistent with the ability of managed care plans to select providers for their network to provide covered services.

We propose to limit payment of capitation rates for enrollees that are provided services while in an IMD (to stays of less than 15 days per month and so long as the IMD is a certain type of facility) for two reasons. First, our proposal seeks to address the specific concerns about ensuring access to and availability of inpatient psychiatric and SUD services that are covered by Medicaid; these concerns have focused on short-term stays. The expansion of the Medicaid program coupled with the overall increase in health care coverage in managed care plans in the Marketplace leads us to expect greater demand on the limited inpatient resources available to provide mental health and SUD services. An estimated 7.1 percent of those aged 18–64 currently meet the criteria for a serious mental illness [4] and an estimated 14.9 percent are currently experiencing serious psychological distress.[5] Further, an estimated 13.6 percent of uninsured individuals aged 18–64 within the Medicaid expansion population currently have a substance use disorder.[6] Similarly, within the Marketplace eligible population, 6.1 percent currently have a serious mental illness, 13.5 percent are experiencing serious psychological distress, and 14.3 percent have a substance use disorder.[7] However, over the past several years the number of beds in freestanding inpatient psychiatric facilities declined by 5 percent with freestanding inpatient psychiatric facilities in urban areas accounting for the majority of the decrease (5.7 percent). In addition, psychiatric beds have decreased significantly over the past 25 years [8] in urban hospitals and distinct part psychiatric units have declined by 9 percent from 2010 to 2013. In addition, newer diversionary services such as crisis residential services have been effective in diverting individuals with psychiatric and substance use disorders experiencing a crisis from emergency departments or inpatient services. We have heard concerns from states and other stakeholders that access to and availability of short-term inpatient psychiatric and SUD services has been compromised and that delays in the provision of care may occur. Managed care plans have an obligation to ensure access to and availability of services under Medicaid regulations for services not prohibited by statute and covered under the contract. To meet that obligation, managed care plans have used alternate settings, including short term crisis residential services, to provide appropriate medical services in lieu of Medicaid-covered settings, they are also dealing with the gap between the need for and the capacity to provide

[4] Serious Mental Illness: Respondents to the NSDUH meet the criteria for SMI in the past year if they have had a diagnosable mental, behavioral, or emotional disorder (excluding developmental and substance use disorders) of sufficient duration to meet diagnostic criteria specified within the 4th edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM–IV) that has resulted in serious functional impairment that substantially interferes with or limits one or more major life activities. Adult NSDUH respondents' mental illness is determined based on modeling their responses to questions on distress (Kessler-6 [K6] scale) and impairment (truncated version of the World Health Organization Disability Assessment Schedule [WHODAS]).

[5] Serious Psychological Distress (SPD): Respondents are determined to have SPD if they have a score of 13 or higher on the Kessler-6 (K6) scale. The Kessler-6 (K6) scale consists of six questions that gather information on how frequently adult respondents experienced symptoms of psychological distress during the past month or during the one month in the past year when they were at their worst emotionally. These questions ask about the frequency of feeling (1) nervous, (2) hopeless, (3) restless or fidgety, (4) sad or depressed, (5) that everything was an effort, and (6) no good or worthless. The NSDUH measure of serious psychological distress results in larger prevalence estimates than the SMI.

[6] Substance Use Disorder (SUD): An adult is defined as having a SUD if they meet the criteria for abuse or dependence for illicit drugs or alcohol. Abuse of illicit drugs or alcohol is defined as meeting one or more of the four criteria for abuse included in the DSM–IV. Dependence on illicit drugs or alcohol is defined as meeting three out of seven dependence criteria (for substances that included questions to measure a withdrawal criterion) or three out of six dependence criteria (for substances that did not include withdrawal questions) for that substance, based on criteria included in DSM–IV. Additional criteria for alcohol and marijuana dependence since 2000 included the use of these substances on 6 or more days in the past 12 months.

[7] Substance Abuse and Mental Health Services Administration (SAMHSA*), Behavioral Health Treatment Needs Assessment Toolkit for States,* available at *http://store.samhsa.gov/shin/content//SMA13-4757/SMA13-4757.pdf.*

[8] New Freedom Commission on Mental Health, *Subcommittee on Acute Care: Background Paper.* DHHS Pub. No. SMA–04–3876. Rockville, MD: 2004.

inpatient and sub-acute psychiatric services.

The second reason we are limiting the payment of capitation rates for enrollees that are provided services while in an IMD is that we believe that section 1905(a)(29)(B) of the Act is applicable to the managed care context. Managed care plans should not be used to provide Medicaid coverage for services not authorized in statute, such as services provided to individuals in an IMD that are not furnished in lieu of a covered service authorized in statute. If an enrollee were a patient in an IMD for an extended period of time, the likelihood that the enrollee would otherwise be incurring authorized Medicaid-covered expenses—and with it, the risk compensated by the capitation payment—decreases. We believe that permitting capitation payments when an enrollee has a short-term stay in an IMD is a means of securing compliance with the statute by delineating parameters for these payments, which we would otherwise exclude or prohibit to achieve compliance with the statute.

Therefore, we propose that capitation payments may be made for a month in which an enrollee receives inpatient services in an IMD for a period of 15 days or less. This 15-day parameter is based on evidence of lengths of stay in an IMD based on data from the Medicaid Emergency Psychiatric Demonstration. This evidence suggests that the average length of stay is 8.2 days.[9] We propose to define a short-term stay as 15 days or less to account for the variability in the length of stay often experienced by individuals who need acute inpatient psychiatric or SUD services. We would expect practice patterns for the same services, whether delivered in an inpatient hospital or an IMD facility would be similar and that such patterns would be monitored by the state. Note that under this proposal, an enrollee could have a length of stay longer than 15 days that covers two consecutive months where the length of stay within each month is less than 15 days, and the MCO or PIHP would be eligible to receive a capitation payment for that enrollee for both months. We considered other alternatives to this approach, including whether to remain silent on a numerical definition associated with a short-term acute stay, or utilizing a number associated with an average length of stay, such as data available under the Medicaid Emergency Psychiatric Demonstration. We request comment on this provision, general approach and methodology, or any other comments. We also request comment on the proposed definition of a short-term acute stay in this context, including the cost of IMD services in FFS or managed care, the wisdom of reflecting a number as either a hard cap on the amount of time for which FFP would be available via the capitation payment, or as an articulation of the average length of stay across a managed care plan's enrollees that would legitimize FFP. We also request comment on ways to operationalize use of an average length of stay in terms of capitation payment development and oversight. In addition, we request comment on the percentage of enrollees that have a length of stay of less than 15 days for inpatient or sub-acute psychiatric services.

For purposes of rate setting, the state and its actuaries may use the utilization of services provided to an enrollee while they have a short term stay as a patient in an IMD to determine an estimate of the utilization of state plan services, that is, inpatient psychiatric services, covered for the enrolled population in future rate setting periods. However, the costs associated with the services to patients in an IMD may not be used when pricing covered inpatient psychiatric services. The IMD utilization must be priced consistent with the cost of the same services through providers included under the state plan. We note that this guidance for accounting for service utilization to patients in an IMD differs from rate setting guidance issued in December 2009 for in lieu of services in the context of home and community based services, *see* CMS, *Providing Long-Term Services and Supports in a Managed Care Delivery System: Enrollment Authorities and Rate Setting Techniques* (December 2009), at page 15, available at *http://www.pasrrassist.org/sites/default/files/attachments/10-07-23/ManagedLTSS.pdf*. In that guidance, we provided that the state may modify the rate-setting process to account for the expected cost as well as utilization of in lieu of services as a proxy for the cost of approved state plan services in a contract. In the context of services rendered to patients in an IMD, we believe such proxy pricing is not consistent with the statutory prohibition of FFP referenced above. As noted earlier, we welcome comment on this proposal.

In proposed paragraph (v), we establish minimum recordkeeping requirements for MCOs, PIHPs, PAHPs, and subcontractors, as applicable, of at least 6 years for data, documentation and information specified in this part. Specifically, we propose that MCOs, PIHPs, PAHPs, and subcontractors retain enrollee grievance and appeal records as specified in § 438.416, base data as specified in § 438.5(c), MLR reports as specified in § 438.8(k), and the documentation specified in § 438.604, § 438.606, § 438.608, and § 438.610. We make this proposal under our authority under section 1902(a)(4) of the Act to mandate methods of administration that are necessary for the efficient operation of the state plan. The retention of these records will aid in monitoring, oversight, and audit activities at the state and federal levels. We request comment on the proposed length of record retention; specifically, whether 6 years is consistent with existing state requirements on managed care plans for record retention and whether we should adopt a different timeframe. We note that MA requires MA organizations to retain records for a period of 10 years at § 422.504(d).

3. Setting Actuarially Sound Capitation Rates for Medicaid Managed Care Programs (§ 438.2, § 438.4, § 438.5, § 438.6, and § 438.7)

Building on a decade of experience with states, we are proposing to improve the effectiveness of the regulatory structure to better assure the fiscal integrity, transparency and beneficiary access to care under the Medicaid program and to promote innovation and improvement in the delivery of services through a comprehensive review of Medicaid managed care capitation rates. The existing regulatory framework is process-based, rather than focused on a substantive review and assessment of the actuarial assumptions and methodologies underlying the development of the rates. Our proposal would strengthen that approach. The overarching goal behind our proposed revisions to the rate-setting framework (proposed in § 438.4 through § 438.7) is to reach the appropriate balance of regulation and transparency that accommodates the federal interests as payer and regulator, the state interests as payer and contracting entity, the actuary's interest in preserving professional judgment and autonomy, and the overarching programmatic goals—shared by states and the federal government—of promoting beneficiary access to quality care, efficient expenditure of funds and innovation in the delivery of care. In addition, we believe that requiring more consistent and transparent documentation of the rate setting process will allow us to conduct more efficient reviews of the rate certification submissions, which is a benefit to all parties.

[9] *http://innovation.cms.gov/Files/reports/MEPD_RTC.pdf*, page 12.

Section 1903(m)(2)(A)(iii) of the Act permits federal matching dollars for state expenditures to a risk bearing entity for Medicaid services when ''such services are provided for the benefit of individuals eligible for benefits under this title in accordance with a contract between the state and the entity under which the prepaid payments to the entity are made on an actuarially sound basis and under which the Secretary must provide prior approval for contracts [meeting certain value thresholds].'' Existing § 438.6(c)(i) elaborates upon the statutory standard to define actuarially sound rates as rates that: (1) Have been developed in accordance with generally accepted actuarial principles and practices; (2) are appropriate for the populations to be covered and the services to be furnished under the contract; and (3) have been certified by an actuary who meets the qualification standards established by the American Academy of Actuaries and follows the practice standards established by the Actuarial Standards Board. In its Actuarial Standard of Practice No. 49, ''Medicaid Managed Care Capitation Rate Development and Certification'' issued in March 2015, the American Academy of Actuaries states that Medicaid capitation rates are ''actuarially sound'' if, for business for which the certification is being prepared and for the period covered by the certification, projected capitation rates and other revenue sources provide for all reasonable, appropriate, and attainable costs. Other revenue sources include, but are not limited to, expected reinsurance and governmental stop-loss cash flows, governmental risk adjustment cash flows, and investment income. Costs include, but are not limited to, expected health benefits, health benefit settlement expenses, administrative expenses, the cost of capital, and government-mandated assessments, fees, and taxes. *See* Actuarial Standard of Practice No. 49 (March 2015), available at *http://www.actuarialstandardsboard.org/wp-content/uploads/2015/03/asop049_179.pdf*. Our proposal to revise the Medicaid managed care rate setting framework expands upon these basic and generally accepted definitions of actuarial soundness to ensure that Medicaid rates are developed in a transparent and consistent manner across Medicaid managed care programs.

We relied on the following principles of actuarial soundness to inform the modernized rate setting framework in this proposed rule. First, capitation rates should be sufficient and appropriate for the anticipated service utilization of the populations and services covered under the contract and provide appropriate compensation to the health plans for reasonable non-benefit costs. Built into that principle is the concept that an actuarially sound rate should result in appropriate payments for both payers (the state and the federal government) and that the rate should promote program goals such as quality of care, improved health, community integration of enrollees and cost containment, where feasible. Second, an actuarial rate certification underlying the capitation rates should provide sufficient detail, documentation, and transparency of the rate setting components set forth in this regulation to enable another actuary to assess the reasonableness of the methodology and the assumptions supporting the development of the final capitation rate. Third, a transparent and uniformly applied rate review and approval process based on actuarial practices should ensure that both the state and the federal government act effectively as fiscal stewards and in the interests of beneficiary access to care.

a. Definitions (§ 438.2)

We propose to define ''actuary'' to incorporate standards for an actuary who is able to provide the certification under current law at § 438.6(c); that is, that the individual meets the qualification standards set by the American Academy of Actuaries as an actuary and follows the practice standards established by the Actuarial Standards Board. We also propose that where the regulation text refers to the development and certification of the capitation rates, and not the review or approval of those rates by CMS, the term actuary refers to the qualified individual acting on behalf of the state. We intend that an actuary who is either a member of the state's staff or a contractor of the state could fulfill this role so long as the qualification and practice standards are also met.

We propose to modify the existing definition of ''capitation payment'' by removing references to ''medical'' services in recognition of the fact that states are contracting with MCOs, PIHPs, and PAHPs for LTSS, which are not adequately captured in the existing definition of capitation payments that refers only to medical services.

We propose to define a ''material adjustment'' as one that, in the objective exercise of an actuary's judgment, has a significant impact on the development of the capitation rate. We note that material adjustments may be large in magnitude, or be developed or applied in a complex manner. The actuary developing the rates should use reasonable actuarial judgment based on generally accepted actuarial principles when assessing the materiality of an adjustment. Further discussion of material adjustments is provided in the discussion on documentation of adjustments in § 438.7 and section I.B.3.c. of this proposed rule.

We also propose to add a definition for ''rate cells.'' The use of rate cells is intended to group people with more similar characteristics and expected health care costs together to set capitation rates more accurately. The rate cells should be developed in a manner to ensure that an enrollee is assigned to one and only one rate cell. That is, each enrollee should be categorized in one of the rate cells and no enrollee should be categorized in more than one rate cell.

b. Actuarial Soundness Standards (§ 438.4)

Consistent with the principles of actuarial soundness described herein, we propose to add a new § 438.4 that builds upon the definition of actuarially sound capitation rates currently at § 438.6(c)(i) and establishes standards for states and their actuaries. In § 438.4(a), we propose to define actuarially sound capitation rates as rates that are projected to provide for all reasonable, appropriate, and attainable costs under the terms of the contract and for the time period and population covered under the contract. Further, we state that the rate development process should be conducted and rates developed in accordance with the proposed standards for approval of rates in § 438.4(b).

Under this provision, costs that are not reasonable, appropriate, or attainable should not be included in the development of capitated rates. Thus, for instance, costs related to improper payments that an MCO, PIHP, or PAHP recovers are not reasonable costs and should not be included as part of the base data used to develop the capitation rate. This is because, consistent with proposed standards in § 438.608(a)(2) and (d)(1) described in section I.B.4.(c) of this proposed rule, MCOs, PIHPs, and PAHPs must report improper payments and recover overpayments they identify from network providers. States must take such recoveries into account when developing capitation rates. Therefore, capitation rates that include the amount of improper payments recovered by an MCO, PIHP, or PAHP as projected costs would not be considered actuarially sound.

In § 438.4(b), we propose to set forth the standards that capitation rates must meet and that we will apply in the review and approval of actuarially sound capitation rates. In § 438.4(b)(1), we propose to redesignate the standard currently in § 438.6(c)(1)(i)(A) that capitation rates have been developed in accordance with generally accepted actuarial principles and practices. We also propose in § 438.4(b)(1) that capitation rates must meet the standards described in proposed § 438.5 dedicated to rate development standards. We acknowledge that states may desire to establish minimum provider payment rates in the contract with the managed care plan. Because actuarially sound capitation rates must be based on the reasonable, appropriate, and attainable costs under the contract, minimum provider payment expectations included in the contract would necessarily be built into the relevant service components of the rate. However, we propose in paragraph (b)(1) to prohibit different capitation rates based on the FFP associated with a particular population. We believe that such practices represent cost-shifting from the state to the federal government and are not based on generally accepted actuarial principles and practices.

In § 438.4(b)(2), we propose to redesignate the provision currently at § 438.6(c)(1)(i)(B). We have restated the standard but the substance is the same: The capitation rates must be appropriate for the population(s) to be covered and the services provided under the managed care contract.

In § 438.4(b)(3), we propose that capitation rates be adequate to meet the requirements on MCOs, PIHPs, and PAHPs in §§ 438.206, 438.207, and 438.208. These sections contain the requirements for MCOs, PIHPs, and PAHPs to ensure availability and timely access to services, adequate networks, and coordination and continuity of care, respectively. The definition of actuarially sound capitation rates in proposed § 438.4(a) provides that the rates must provide for all reasonable, appropriate, and attainable costs that are required under the contract. The maintenance of an adequate network that provides timely access to services and ensures coordination and continuity of care is an obligation on the managed care plans for ensuring access to services under the contract. In the event concerns in these areas arise, the review of the rate certification would explore whether the provider rates are sufficient to support the MCO's, PIHP's, or PAHP's obligations. We solicit comments on this proposal.

In § 438.4(b)(4), we propose that capitation rates be specific to the payment attributable to each rate cell under the contract. The rates must appropriately account for the expected benefit costs for enrollees in each rate cell, and for a reasonable amount of the non-benefit costs of the plan. Payments from any rate cell must not be expected to cross-subsidize or be cross-subsidized by payments for any other rate cell. In accordance with the existing rule in § 438.6(c)(2)(i), we propose that all payments under risk contracts be actuarially sound and that the rate for each rate cell be developed and assessed according to generally accepted actuarial principles and practices. *See* 67 FR 40989, 40998. We now propose to make this a more explicit standard in the regulation text in paragraph (b)(3) to eliminate any potential ambiguity on this point and to be consistent with our goal to make the rate-setting and rate approval process more transparent. Some states use rate ranges as a tool that allows the submission of one actuarial certification but permits further negotiation with each of the MCOs, PIHPs, and PAHPs within the rate range. Historically, we have permitted that any rate paid to any managed care plan within the certified range will be determined to be actuarially sound regardless of where it fell in the range. However, the rate ranges may be quite large. States have not had to submit additional documentation to CMS as long as the final payment rate was within the certified rate range. Additionally, states have used rate ranges to increase or decrease rates paid to the managed care plans without providing further notification to CMS or the public of the change or certification that the change was based on actual experience incurred by the MCOs, PIHPs, or PAHPs that differed in a material way from the actuarial assumptions and methodologies initially used to develop the capitation rates. In this rule, we propose to alter past practices moving forward such that:

- Each individual rate paid to each MCO, PIHP, or PAHP be certified as actuarially sound with enough detail to understand the specific data, assumptions, and methodologies behind that rate.
- States may still use rate ranges to gauge an appropriate range of payments on which to base negotiations but states will have to ultimately provide certification to CMS of a specific rate for each rate cell, rather than a rate range. While we understand that this will impact some states that rely heavily on rate ranges, we believe that requiring the details, including the specific data, assumptions, and methodologies, behind each contracted rate strengthens program integrity and transparency in the rate setting process. We request comment on this approach.

This proposed change and the impact on our review of the rate-setting process would give CMS, the states, and taxpayers more confidence that Medicaid capitation payments are proper for the services and populations covered, are supportive of beneficiary access to quality care, and are an efficient use of Medicaid funds.

In proposed § 438.4(b)(5), we propose to redesignate the standard in current § 438.6(c)(1)(i)(C) that an actuary certify that the rate methodology and the final capitation rates are consistent with the standards of this part and generally applicable standards of actuarial practice. This would require that all components and adjustments of the rate be certified by the actuary. In addition, the actuary would certify the rate for each rate cell under the contract. Under our proposal, a rate certification of a general rate range would not be sufficient. Also, we reiterate that for this standard to be met, the individual providing the certification must be within our proposed definition of ''actuary'' in § 438.2.

As proposed, § 438.4(b)(6) would incorporate the special contract provisions related to payment proposed in § 438.6 if such provisions were applied under the contract. As discussed in this rule, we propose to codify in § 438.6 the rules for risk-sharing mechanisms, incentive arrangements, withhold arrangements, and delivery system and provider payment initiatives under MCO, PIHP, or PAHP contracts.

Proposed § 438.4(b)(7) incorporates the documentation standards proposed in § 438.7. We believe that for us to assess the actuarial soundness of capitation rates the data, methodologies, and assumptions applied by the actuary must be sufficiently and transparently documented. Clear documentation will support the goal of instituting a meaningful and uniformly applied rate review and approval process and will streamline the process for both states and CMS. Again, we believe that the elements of actuarial soundness specified in proposed § 438.4—and the more detailed standards in proposed §§ 438.5, 438.6 and 438.7—are consistent with the prevailing and generally accepted actuarial practices for Medicaid rate setting.

In proposed § 438.4(b)(8), we propose to include a new standard that actuarially sound capitation rates for MCOs, PIHPs, and PAHPs must be

developed so that MCOs, PIHPs, and PAHPs can reasonably achieve a minimum MLR of at least 85 percent, and if higher, a MLR calculation that provides for reasonable administration costs when using the calculation defined in proposed § 438.8. See section I.B.1.c.(1) of this proposed rule for additional discussion of this proposal. States could establish higher MLR standards, either for rate development purposes or to measure actual performance of the managed care plan, or both. We believe this minimum standard, which is consistent with MLR standards for both commercial and MA organizations, balances the goal of ensuring enrollees are provided appropriate services while also ensuring a cost effective delivery system. As a result of this standard, the reports from MCOs, PIHPs, and PAHPs on the MLR would be integral sources of data for rate setting. For instance, states that discover, through the MLR reporting under proposed § 438.8(k), that an MCO, PIHP, or PAHP has not met an MLR standard of at least 85 percent would need to take this into account and include adjustments in future year rate development. We believe that such adjustments to account for a lower MLR ensure ongoing actuarial soundness. All such adjustments would need to comply with all standards around adjustments discussed in section I.B.3.c. of this proposed rule.

Through this proposed rule, as we codify and revise standards for states and their actuaries for the development of Medicaid capitation rates our aim is to offer flexibility in setting rates to foster efficiency, quality and innovation. We solicit comment whether these standards are adequate for this purpose and the goals discussed in this proposed rule. Also, we request comment on methods, measures, and data sources that the states and their actuaries can use to assess whether capitation rates are adequate to support provider reimbursement levels that result in managed care plan provider networks that satisfy the network adequacy and timely access standards in proposed §§ 438.68 and 438.206.

c. Rate Development Standards (§ 438.5)

In § 438.5(a), we propose to establish definitions for terms of significance to the standards for rate development and documentation in the rate certification as proposed in § 438.7(b). We propose to add definitions for ''budget neutral,'' ''prospective risk adjustment,'' ''retroactive risk adjustment,'' and ''risk adjustment.''

We propose to define ''budget neutral'' in accordance with the generally accepted usage of the term as applied to risk sharing mechanisms, as meaning no aggregate gain or loss across the total payments made to all managed care plans under contract with the state. We propose to define ''risk adjustment'' as a methodology to account for health status of enrollees covered under the managed care contract. We propose that the definitions for ''prospective risk adjustment'' and ''retrospective risk adjustment'' clarify when the risk adjustment methodology is applied to the capitation rates under the contract.

In § 438.5(b), we set forth the steps a state, acting through its actuary, would have to follow when establishing Medicaid managed care capitation rates. These proposed standards are based on furthering the goals of transparency, fiscal stewardship, and beneficiary access to care. We believe setting clear standards and expectations for rate development, which are to be documented in the rate certification as described in proposed § 438.7(b), would—without restricting appropriate flexibility for states to drive program improvements through managed care contracting—support managed care systems that can operate efficiently, effectively, and with a high degree of fiscal integrity. These goals would underlie our interpretation and guidance on the rules adopted to govern rate-setting for MCOs, PIHPs, and PAHPs.

Paragraph (b) of this section generally proposes the steps that would be necessary for developing actuarially sound capitation rates with specific standards for the steps outlined in proposed paragraphs (c) through (g). We based these steps on our understanding of how actuaries approach rate setting with modifications to accommodate our proposal as to what actuarial soundness should include in the context of Medicaid managed care. We solicit comment on whether additional or alternative steps are more appropriate to meet the stated goals for establishing standards for rate setting. We do not intend for these steps to be followed in the order listed in this proposed rule, but we would stipulate that the rate setting process include each step and follow the standards for each step. In reviewing and approving rates under this proposal, we would evaluate each step and states would have to explain why any one of the steps was not followed or was not applicable. The six steps include:

- Collect or develop appropriate base data from historical experience;
- Develop and apply appropriate and reasonable trends to project benefit costs in the rating period, including trends in utilization and prices of benefits;
- Develop appropriate and reasonable projected costs for non-benefit costs in the rating period as part of the capitation rate;
- Make appropriate and reasonable adjustments to the historical data, projected trends, or other rate components as necessary to establish actuarially sound rates;
- Consider historical and projected MLR of the MCO, PIHP, or PAHP; and
- For programs that use a risk adjustment process, select an appropriate risk adjustment methodology, apply it in a budget neutral manner, and calculate adjustments to plan payments as necessary.

In § 438.5(c), we propose standards for selection of appropriate base data. In paragraph (c)(1), we propose that, for purposes of rate setting, states provide to the actuary Medicaid-specific data such as validated encounter data, FFS data (if applicable), and audited financial reports for the 3 most recent years completed prior to the rating period under development. In proposed § 438.5(c)(2), we propose that the actuary exercise professional judgment to determine which data is appropriate after examination of all data sources provided by the state, setting a minimum parameter that such data be derived from the Medicaid population or derived from a similar population and adjusted as necessary to make the utilization and cost data comparable to the Medicaid population for which the rates are being developed. We propose that the data that the actuary uses must be from the 3 most recent years that have been completed prior to the rating period for which rates are being developed. For example, for rate setting activities in 2016 for calendar year 2017, the data used must at least include data from calendar year 2013. We understand that claims may not be finalized for 2015 and we would expect the actuary to make appropriate and reasonable judgments as to whether 2013 or 2014 data, which would be complete, must account for a greater percentage of the base data set. We use a calendar year for ease of reference in the example, but a calendar year is interchangeable with the state's contracting cycle period (for example, state fiscal year). We understand that there may be reasons why older data are necessary to inform certain trends or historical experience containing data anomalies, but the primary source of utilization and price data should be no older than the most recently completed 3 years. Noting that states may not be able to meet the

standard in proposed paragraph (c)(2) for reasons such as a need to transition into these new standards or for an unforeseen circumstance where data meeting the proposed standard is not available, we propose an exception in the regulation to accommodate such circumstances. Under our proposal in § 438.5(c)(3)(i) and (ii), the state may request an exception to the provision in paragraph (c)(2) that the basis of the data be no older than from the three most recent and complete years prior to the rating period provided that the state submits a description of why an exception is needed and a corrective action plan with the exception request that details how the problems will be resolved in no more than 2 years after the rating period in which the deficiency was discovered, as proposed in § 438.5(c)(3)(ii). We believe that 2 years is enough time for states to work with their contracted managed care plans or repair internal systems to correct any issues that impede the collection and analysis of recent data. We request comment on this proposed standard and our assumption about the length of time to address data concerns that would prevent a state from complying with our proposed standard.

Proposed § 438.5(d) addresses standards for trend factors in setting rates. Specifically, we propose that trend factors be reasonable and developed in accordance with generally accepted actuarial principles and practices. We also stipulate that trend factors be developed based on actual experience from the same or similar populations. We propose specific standards for the documentation of trend factors in proposed § 438.7(b)(2). We request comment on whether we should establish additional parameters and standards in this area.

Proposed paragraph (e) would establish standards for developing the non-benefit component of the capitation rate, which includes expenses related to administration, taxes, licensing and regulatory fees, reserve contributions, profit margin, cost of capital, and other operational costs. The only non-benefit costs that may be recognized and used for this purpose are those associated with the MCO's, PIHP's, or PAHP's provision of state plan services to Medicaid enrollees; this proposal is consistent with our proposal at § 438.3(c) that capitation rates be based only on services covered under the state plan.

In paragraph (f), we propose to address adjustments. Adjustments are important for rate development and may be applied at almost any point in the rate development process. For purposes of this proposed rule, we have separated risk adjustment from all other adjustments, and specific standards for risk adjustment are proposed in paragraph (g) of this section. Proposed standards for adjustments are set forth in § 438.5(f). We believe that most adjustments applied to Medicaid capitation rate development would reasonably support the development of accurate data sets for purposes of rate setting, address appropriate programmatic changes, the health status of the enrolled population, or reflect non-benefit costs. For additional discussion on acuity adjustments to account for the health status of the enrolled population, refer to the content on risk adjustment in section I.B.3.e of the preamble. We considered identifying specific adjustments we find permissible in the regulations instead of requiring additional justification, but believe that such an approach might foreclose the use of reasonable adjustments. We request comment on this approach.

In proposed paragraph (g), we propose to set forth standards for risk adjustment. In general, risk adjustment is a methodology to account for the health status of enrollees when predicting or explaining costs of services covered under the contract for defined populations or for evaluating retrospectively the experience of MCOs, PIHPs, or PAHPs contracted with the state.

States currently apply the concept of ''risk adjustment'' in multiple ways and for multiple purposes. In some cases, states may use risk adjustment as the process of determining and adjusting for the differing risk between managed care plans. In other cases, states may use risk adjustment as the process of determining the relative risk of the total enrolled population compared to a standard population (for example, the enrolled population from a prior rating period.) For purposes of this regulation, we consider the first case to be the concept of risk adjustment as described in § 438.5(a) and § 438.5(g). We consider the second case to be an acuity adjustment subject to the proposed standards for adjustments in § 438.5(f). Risk adjustment may be conducted in one of two ways. First, a state may use historical data to adjust future capitation payments. This is risk adjustment conducted on a prospective basis. Second, a state may perform a reconciliation and redistribution of funds based on the actual experience in the rating period. This is risk adjustment conducted on a retrospective basis. In § 438.5(g), we propose that prospective or retrospective risk adjustment be budget neutral. This is a proposed redesignation and renaming of the standard that such mechanisms be cost neutral in the current § 438.6(c)(1)(iii). The proposed documentation standards in the certification would depend on the type of risk adjustment chosen and are discussed in proposed § 438.7(b)(4).

d. Special Contract Provisions Related to Payment (§ 438.6)

We propose, at § 438.6, contract standards related to payments to MCOs, PIHPs, and PAHPs, specifically, risk-sharing mechanisms, incentive arrangements, and withhold arrangements. This section builds upon, and proposes minor modifications to the special contract provisions that are currently codified at § 438.6(c)(5). We propose, at paragraph (a), three definitions applicable to this section. The definition for an ''incentive arrangement'' is unchanged from the definition that is currently codified in § 438.6(c)(1)(iv). We propose a definition for ''risk corridor'' with a slight modification from the existing definition at § 438.6(c)(1)(v). The current definition specifies that the state and the contractor share in both profits and losses outside a predetermined threshold amount. Experience has shown that states employ risk corridors that may apply to only profits or losses. We therefore propose to revise the definition to provide flexibility that reflects that practice. We also propose to add a definition for ''withhold arrangements,'' which would be defined as a payment mechanism under which a portion of the capitation rate is paid after the MCO, PIHP, or PAHP meets targets specified in the contract. Our current regulation is silent on this increasingly popular payment mechanism and we propose with this rule to acknowledge and add standards governing such arrangements.

In proposed paragraph (b), we would establish the basic standards for programs that apply risk corridor or similar risk sharing arrangements, incentive arrangements, and withhold arrangements. In § 438.6(b)(1), we propose to redesignate the existing standard (in current § 438.6(c)(2)) that the contract include a description of any risk sharing mechanisms, such as reinsurance, risk corridors, or stop-loss limits, applied to the MCO, PIHP, or PAHP. Although the proposed regulation text includes these examples, this list is not exhaustive and we intend to interpret and apply this regulation to any mechanism or arrangement that has the effect of sharing risk between the MCO, PIHP, or PAHP and the state.

Given the new proposed standards on a minimum MLR in § 438.8, we believe that states should consider the parameters of the minimum MLR when developing any risk sharing mechanisms to ensure upper and lower bounds are within those MLR standards but we have not made that a standard. We request comment on this approach.

In § 438.6(b)(2), we propose to redesignate the existing standards for incentive arrangements currently stated in § 438.6(c)(5)(iii), but with a slight modification. We believe that the existing regulatory standards that incentive arrangements be time-limited and not subject to automatic renewal, available to both public and private contractors, not conditioned on intergovernmental transfer (IGT) agreements, necessary for the specified activity, and limited to 5 percent of the certified capitation rate are appropriate standards, as they support the fiscal integrity of the capitation rate and the development of quality and outcome-based initiatives. However, we believe that an additional standard is appropriate. We propose to add a new standard in § 438.6(b)(2)(v) that incentive arrangements would have to be designed to support program initiatives tied to meaningful quality goals and performance measure outcomes. We believe this change would support delivery system reform initiatives that include incentive arrangements for quality goals and outcomes. We also clarify that not conditioning the incentive payment on IGTs means that the health plan's receipt of the incentive is solely based on satisfactory performance and not conditioned on the health plan's compliance with an IGT agreement. We request comment as to whether the existing upper limit (5 percent) on the amount attributable to incentive arrangements is perceived as a barrier to designing performance initiatives and achieving desired outcomes and whether CMS must continue to set forth expectations for incentive arrangements between the state and contracted health plans.

Unlike incentive arrangements that are an add-on to the base capitation rate received by the MCO, PIHP, or PAHP, a withhold arrangement is an amount retained by the state from the base capitation rate payable to the MCO, PIHP, or PAHP; the withhold amount is paid based on satisfactory performance of specified measures or outcomes related to the contract. In paragraph (b)(3), we propose that the capitation rate under the contract with the MCO, PIHP, or PAHP, minus any portion of the withhold amount that is not reasonably achievable, must be certified as actuarially sound. For example, if the contract permits the state to hold back 3 percent of the final capitation rate under the contract, or 3 percent from a particular rate cell of the capitation rate under the contract, the actuary must determine the portion of the withhold that is reasonably achievable. We request comment on how an actuary would conduct such an assessment to inform future guidance in this area. If the actuary determines that only two thirds of the withhold is reasonably achievable (that is, 2 percent of the final contract capitation rate), the capitation rate, minus the portion that is not reasonably achievable (that is, 1 percent of the final capitation rate), must be actuarially sound. Thus, the total amount of the withhold, achievable or not, must be reasonable and take into account an MCO's, PIHP's, or PAHP's capital reserves and financial operating needs for expected medical and administrative costs. When determining the reasonableness of the amount of the withhold, the actuary should also consider the cash flow requirements and financial operating needs of the MCOs, PIHPs, and PAHPs, taking into account such factors as the size and characteristics of the populations covered under the contract. The reasonableness of the amount of the withhold should also reflect an MCO's, PIHP's, or PAHP's capital reserves as measured by risk-based capital levels or other appropriate measures (for example, months of claims reserve) and ability of those reserves to address expected financial needs. The data, assumptions, and methodologies used to determine the portion of the withhold that is reasonably achievable must be included in the documentation for rate certification specified under § 438.7(b). We note that the proposed terms for the design of the withhold arrangement mirror the terms for incentive arrangements minus the upper limit, as the rate received by the MCO, PIHP, or PAHP absent the portion of withhold amount that is not reasonably achievable must be certified as actuarially sound. We believe that incentive and withhold arrangements are two approaches to drive health plan performance toward specified goals or outcomes. While we understand the legitimate uses for withhold arrangements, we are concerned that an excessively large withhold could inappropriately reduce the amount received by an MCO, PIHP, or PAHP on a prepaid basis to the extent that the amount is insufficient to cover expected benefit costs, which would result in rates that are not actuarially sound. The proposed regulations are designed to ensure that any withhold arrangements meet the following goals: (1) The withhold arrangement does not provide an opportunity for MCOs, PIHPs, or PAHPs to receive more than the actuarially certified capitation rate; (2) the withhold arrangement provides MCOs, PIHPs, and PAHPs an opportunity to reasonably achieve an amount of the withhold, such that if the state had set the capitation rate at the actual amount paid after accounting for the effect of the withhold, it would be certifiable as actuarially sound; and (3) the actuarial soundness of the capitation rates after consideration of the withhold arrangement is assessed at an aggregate level, across all contracted MCOs, PIHPs, or PAHPs. We welcome comment on appropriate approaches to evaluating the reasonableness of these arrangements and the extent to which the withholds are reasonably achievable and solicit comment on whether our prorposed regulation text sufficiently accomplishes our stated goals.

We propose to redesignate the existing standard at § 438.6(c)(5)(v) related to adjustments to actuarially sound capitation rates to account for graduate medical education (GME) payments authorized under the state plan at the proposed § 438.6(b)(4) without any changes to the substantive standard.

We propose to add a new paragraph (c) to § 438.6 to formalize our longstanding policy on the extent to which a state may direct the MCO's, PIHP's or PAHP's expenditures under a risk contract. Existing standards in § 438.6(c)(4) (proposed to be redesignated as § 438.3(c)) limit the capitation rate paid to MCOs, PIHPs, or PAHPs to the cost of state plan services covered under the contract and associated administrative costs to provide those services to Medicaid eligible individuals. Furthermore, under § 438.60, the state must ensure that additional payments are not made to a provider for a service covered under the contract other than payment to the MCO, PIHP or PAHP with specific exceptions. Current CMS policy has interpreted these regulations to mean that the contract with the MCO, PIHP or PAHP defines the comprehensive cost for the delivery of services under the contract, and that the MCO, PIHP or PAHP, as risk-bearing organizations, maintain the ability to fully utilize the payment under that contract for the delivery of services. In paragraph (c)(1), we propose the general rule that the state may not direct the MCO's, PIHP's,

or PAHP's expenditures under the contract.

However, we also want to encourage states to use health plans as partners to assist the states in achieving overall delivery system and payment reform and performance improvements. We also want states to be able, at their discretion, to incentivize and retain certain types of providers to participate in the delivery of care to Medicaid beneficiaries under a managed care arrangement. Managed care plans are a key partner in achieving the goals of improved population health and better care at lower cost. We are therefore proposing in paragraphs (c)(1)(i) through (c)(1)(iii), ways that a state may set parameters on how expenditures under the contract are made by the MCO, PIHP, or PAHP. Proposed paragraph (c)(1)(i) provides that states may specify in the contract that managed care plans adopt value-based purchasing models for provider reimbursement. In this approach, the contract between the state and the managed care plan would set forth methodologies or approaches to provider reimbursement that prioritize achieving health outcomes versus simply the delivery of services. Implementing this flexibility in regulation would assure that these regulations promote paying for quality or health outcomes rather than the volume of services. These proposed flexibilities support states and Medicaid managed care plans to adopt and build upon the 30/50 and 85/90 value-based payment targets established by HHS for the Medicare FFS program for 2016–2018.[10] These targets for the Medicare FFS program involve value-based provider reimbursement. Medicaid managed care programs across the country provide integrated and coordinated systems of health care to Medicaid beneficiaries and value-based purchasing models are a tool that states and Medicaid managed care plans can use to achieve and sustain better care at lower costs. In paragraph (c)(1)(ii), we reiterate that states have the flexibility to require managed care plan participation in broad-ranging delivery system reform or performance improvement initiatives. This approach would permit states to specify in the contract that MCOs, PIHPs, or PAHPs participate in multi-payer or Medicaid-specific initiatives, such as patient-centered medical homes, efforts to reduce the number of low birth weight babies, broad-based provider health information exchange projects, and delivery system reform projects to improve access to services, among others. For example, states could make available incentive payments for the use of technology that supports interoperable health information exchange by network providers that were not eligible for EHR incentive payments under the HITECH Act (for example, long-term/post-acute care, behavioral health, and home and community based providers). The state would be permitted to use the health plan payments as a tool to incentivize providers to participate in particular initiatives that operate according to state-established and uniform conditions for participation and eligibility for additional payments. The capitation rates to the health plans would reflect an amount for incentive payments to providers for meeting performance targets, however the health plans retain control over the amount and frequency of payments. We believe that this approach balances the need to have a health plan participate in a multi-payer or community-wide initiative, while giving the health plan a measure of control to participate as an equal collaborator with other payers and participants. We also clarify that because funds associated with delivery system reform or performance initiatives are part of the capitation payment, any unspent funds remain with the MCO, PIHP, or PAHP. This approach ensures that any additional payment is associated with a value relative to innovation and statewide reform goals.

Proposed paragraph (c)(1)(iii) would support two state practices critical to ensuring timely access to high-quality, integrated care, specifically: (1) Setting minimum reimbursement standards or fee schedules for providers that deliver a particular covered service; and (2) raising provider rates in an effort to enhance the accessibility or quality of covered services. For example, some states have opted to continue paying primary care providers at Medicare reimbursement rates under section 1202 of the Affordable Care Act for calendar years 2013–2014. Because actuarially sound capitation rates are based on all reasonable, appropriate and attainable costs (see section I.B.3.b. of this proposed rule), the contractual expectation that primary care providers would be paid at least according to Medicare reimbursement levels must be accounted for in pricing the primary care component of the capitation rate. These amounts would be subject to the same actuarial adjustments as the service component of the rate and would be blended into the final contract rate certified by the actuary. Under the contract, the state would direct the MCO, PIHP, or PAHP to adopt a minimum fee schedule created by the state for services rendered by that class of providers This proposal is reflected in paragraph (c)(1)(iii)(A).

In proposed paragraph (c)(1)(iii)(B), we note the state could specify a uniform dollar or percentage increase for all providers that provide a particular service under the contract. This option would have the state treat all providers of the services equally and does not permit the state to direct the MCO, PIHP, or PAHP to reimburse specific providers specific amounts at specified intervals. We believe this option would help ensure that additional funding is directed toward enhancing services and ensuring access rather than benefitting particular providers. It would also support the standard that total reimbursement to a provider is based on utilization and the quality of services delivered. Finally, we believe that this option would be consistent with and build upon the existing standard that the capitation rate reflects the costs of services under the contract. Under both approaches in (c)(1)(iii), the MCO, PIHP or PAHP would be permitted to negotiate higher payment amounts under their specific provider agreements.

To ensure that state direction of expenditures promotes delivery system or provider payment initiatives, we expect that states will, as part of the federal approval process, demonstrate that such arrangements are based on utilization and the delivery of high-quality services, as specified in paragraph (c)(2)(i)(A). Our review will also ensure that state directed expenditures support the delivery of covered services. Consequently, we expect that would demonstrate that all providers of the service are being treated equally, including both public and private providers, as specified in paragraph (c)(2)(i)(B). The ultimate goal for state-directed expenditures is to support improved population health and better care at lower cost. These efforts cannot occur in isolation. Therefore, in paragraph (c)(2)(i)(D), we would link approval of the arrangement to supporting at least one of the objectives in the comprehensive quality strategy in § 438.340 (proposed paragraph (c)(2)(i)(C)) and that the state would implement an evaluation plan to measure how the arrangement supports that objective (proposed paragraph (c)(2)(i)(D)). This will enable us and states to demonstrate that these

[10] *See, e.g.,* Burwell, Sylvia M., ''Setting Value-Based Payment Goals—HHS Efforts to Improve U.S. Health Care,'' N. Engl. J. Med. at 1 (January 27, 2015).

arrangements are effective in achieving their goals. In proposed paragraph (c)(2)(i)(E), we would not permit provider participation in these arrangements to be conditioned on intergovernmental transfer agreements so that the arrangement remains focused on proactive efforts to improve care delivery and reduce costs. Finally, in proposed paragraph (c)(2)(i)(F), because we seek to evaluate and measure the impact of these reforms, such agreements would not be renewed automatically. We establish standards in proposed paragraphs (c)(2)(i) and (c)(2)(ii) for our approval of permitted state direction of expenditures for delivery system or provider payment initiatives to ensure that the arrangement is consistent with the specific provisions of this section.

Under proposed paragraph (c)(2)(ii), any contract arrangement that directs expenditures made by the MCO, PIHP, or PAHP under paragraphs (c)(1)(i) or (c)(1)(ii) for delivery system or payment provider initiatives would use a common set of performance measures across all payers and providers. Having a set of common performance measures would be critical to evaluate the degree to which multi-payer efforts achieve the stated goals of the collaboration. We seek comment on the proposed general standard, and the three exceptions, providing a state the ability to direct MCO's, PIHP's, or PAHP's expenditures. Specifically, we seek comment on the extent to which the three exceptions are adequate to support efforts to improve population health and better care at lower cost, while maintaining MCO's, PIHP's or PAHP's ability to fully utilize the payment under that contract for the delivery of services to which that value was assigned.

We also take this opportunity to clarify that the regulations in part 438 are not a barrier to the operation of programs that promote wellness among beneficiaries by Medicaid managed care plans. Positive incentives to promote wellness among the Medicaid population can help promote health and well-being and improve health outcomes. States and managed care plans that undertake efforts to reward beneficiary health care decisions and behaviors through inexpensive gifts or services are, however, advised to consult OIG guidance for compliance with section 1128A(a)(5) of the Act. *See,* for example, OIG, *Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries* (August 2002), available at *http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf.*

e. Rate Certification Submission (§ 438.7)

In new § 438.7, we propose the content of the rate certification that is submitted by the state for CMS review and approval. This section is distinguished from the rate development standards in § 438.5 in that it focuses on documentation of rate development as opposed to the actual steps taken by states and actuaries to develop capitation rates. This section includes a new proposal that states receive CMS' approval of the rate certification in addition to the contract, as provided in § 438.3(a). The rate certification is part of the procedural mechanism for CMS to ensure that the capitated rates payable to MCOs, PIHPs, and PAHPs are actuarially sound as specified in section 1903(m)(2)(A)(iii) of the Act. We propose that rate certifications in § 438.7(a) follow the same procedures as for contract submissions through a cross-reference to § 438.3(a). Our proposal therefore includes the regulatory flexibility to set forth timeframes and more detailed processes for the submission of the rate certification review and approval process in subregulatory guidance, which is in addition to the specific proposed standard that states seeking contract and rate approval prior to an anticipated effective date should submit such contracts and rate certifications to CMS no later than 90 days before anticipated effective date. We believe that review and approval of the rate certification separate from the approval of a contract is an integral step to work with states to ensure appropriate rates under these programs and to modernize our oversight of Medicaid managed care rate setting practices. In addition, we believe that this approach will streamline the approval process as the rate certification supports the payment terms in the contract. We believe that section 1903(m)(2)(A)(iii) authorizes us to stipulate review and approval of both the contract and the rate certification for MCOs as the contract must include the payment rates, which are developed via the rate certification. Consistent with existing standards for CMS review and approval for PIHP and PAHP contract in § 438.6(a) (redesignated as § 438.3(a) in this proposed rule), we propose to extend the review and approval standards for the rate certification for PIHPs and PAHPs under our authority under section 1902(a)(4) of the Act. As proposed here, the rate certification describes and provides the necessary documentation and evidence that the rates were developed consistent with generally accepted actuarial principles and practices and regulatory standards. In the event that the certification and the contract are submitted to CMS at different times, we would approve the rate certification prior to approval of the contract, but FFP for the program is contingent upon approval of the contract. This process would satisfy CMS' statutory authority to oversee the Medicaid program and to ensure that capitation rates are actuarially sound, which in turn helps states and health plans to improve access to and quality of care for Medicaid beneficiaries.

Proposed § 438.7(b) would set forth the content that must be in the rate certification to initiate the CMS review process. As proposed in paragraph (b)(1), the certification would describe the base data. The rate certification would describe how the actuary used professional judgment to determine which data was appropriate after examination of all data sources and the data sources used, as well as reasons if the other data sources provided to the actuary were not used in the rate development process.

In proposed paragraph (b)(2), we propose specific documentation standards for trend factors. We propose that the rate certification be detailed enough so that CMS or an actuary can understand and evaluate the development and reasonableness of the trend and any meaningful differences among trend factors applied across rate cells, populations, or services. In proposed paragraph (b)(3), we propose that the basis for determining the non-benefit component of the rate must be included in the actuarial certification with enough detail so CMS or an actuary can understand each type of non-benefit expense and evaluate the reasonableness of each cost assumption underlying each non-benefit expense.

In proposed paragraphs (b)(4)(i) through (iii), we propose standards for transparency in the rate certification on how the material adjustments were developed and the reasonableness of the adjustment for the population, the cost impacts of each material adjustment and where in the rate development process the adjustment was applied. We understand there may be multiple adjustments applied in the rate-setting process, ranging from minor adjustments, which on their own do not impact the overall rate by a material amount, to other adjustments, which may be much greater in scope and magnitude. Therefore, we have proposed that states only provide information on the development of and cost impact for each of the material adjustments. Adjustments that do not meet this threshold, or non-material

adjustments, may be aggregated and only the cost impact of that aggregated bundle would need to be shown in the certification as set forth in proposed paragraph (b)(4)(ii). In § 438.7(b)(4)(iv), we propose that the actuarial certification include a list of all the non-material adjustments used in rate development, but specifics of each non-material adjustment will not be necessary. As we gain experience in reviewing adjustments consistent with these standards and further consult with states, we may issue guidance on what we believe to be material and non-material adjustments, but until that time, we would expect the actuary to exercise reasonable judgment and good faith when characterizing or treating an adjustment as material or non-material.

In paragraph (b)(5), we propose to establish documentation standards in the certification for prospective and retrospective risk adjustment. In paragraph (b)(5)(i), we propose that the rate certification should include sufficient detail of the prospective risk adjustment methodology because the methodology is an integral part of the rate development process. To evaluate the appropriateness of the prospective risk adjustment methodology, we propose that the following specific pieces of information be included in the rate certification: The model selected and data used by the state; the method for calculating the relative risk factors and the reasonableness and appropriateness of the method in measuring the risk of the respective populations; the magnitude of the adjustment on the capitation rate for each MCO, PIHP, or PAHP; and an assessment of the predictive value of the methodology compared to prior rating periods, and any concerns the actuary may have with the risk adjustment process. Retrospective risk adjustment methodologies are calculated and applied after the rates are certified; however, we propose in § 438.7(b)(5)(ii) that the certification must document who is calculating the risk adjustment; the timing and frequency of the risk adjustment; the model and the data to be used and any adjustments to them; and any concerns the actuary may have with the risk adjustment process. For either approach to risk adjustment, our proposal would require adjustment to be budget neutral under § 438.5(b)(6).

Use of the risk adjustment model as a method to retrospectively increase or decrease the total payments across all Medicaid managed care plans based on the overall health status or risk of the population would not be permitted. Such retrospective increases or decreases in the total payments do not meet the standard in § 438.5(g) that the risk adjustment methodology be developed in a budget neutral manner. We believe that an adjustment applied to the total payments across all health plans to account for significant uncertainty about the health status or risk of a population is an acuity adjustment, which is a permissible adjustment under § 438.5(f), but would need to be documented under proposed paragraph (b)(4) of this section regarding adjustments. While retrospective acuity adjustments may be permissible, they are intended solely as a mechanism to account for differences between assumed and actual health status when there is significant uncertainty about the health status or risk of a population, such as: (1) New populations coming into the Medicaid program; or (2) a Medicaid population that is moving from FFS to managed care when enrollment is voluntary and there may be concerns about adverse selection. In the latter case, there may be significant uncertainty about the health status of which individuals would remain in FFS versus move to managed care; although this uncertainty is expected to decrease as the program matures.

In § 438.7(b)(6), we propose that the rate certification include a description of any of the special contract provisions related to payment in proposed § 438.6, such as risk sharing mechanisms and incentive or withhold arrangements.

In paragraph (c), we propose the rate certification standards for rates paid under risk contracts. In paragraph (c)(1), we acknowledge that states may pay different capitation rates to different plans; for example, some states already account for differences in final capitation rates paid to contracted managed care plans through risk adjustment. States that choose to pay different rates to plans for factors such as differing administrative assumptions, service area adjustments or other non-risk adjustment methodologies will need to provide documentation for the different assumptions used in the development of each of the individual rates paid to each plan. While such variations are permissible, we take this opportunity to remind states as reflected and strengthened in this proposed rule, that all payment rates must be actuarially sound under existing law.

In § 438.7(c)(2), we propose to establish parameters for retroactive adjustments to capitation rates paid under the risk contract. Specifically, we propose that the state submit a revised rate certification (and contract amendment) that describes the specific rationale, data, assumptions, and methodologies of the adjustment in sufficient detail to understand and evaluate the proffered retroactive adjustments to the payment rate. All such adjustments are also subject to federal timely filing standards for federal financial participation.

In paragraph (d), we propose to require states to include additional information in the rate certification if pertinent to CMS' approval of the contract rates and to identify whether that additional information, which may supplement the rate certification, is proffered by the state, the actuary, or another party. We believe that clarifying our expectations and setting parameters for consistent and transparent documentation of the rate setting process will allow CMS to conduct more efficient reviews of the rate certification submissions and to expedite the approval process.

We propose to remove the standard currently at § 438.6(c)(4)(iii) that states document the projected expenditures under the proposed contract compared to the prior year's contract, or with FFS if the managed care program is new. We do not believe that this information is integral to the review of the rate certification or contract and that such information can be reasonably calculated by CMS if necessary.

4. Other Payment and Accountability Improvements

a. Prohibition of Additional Payments for Services Covered Under MCO, PIHP, or PAHP Contracts (§ 438.60)

We propose a new heading for § 438.60 and to make minor revisions to the regulatory text to clarify the intent of the prohibition of additional payments to network providers that are contracted with an MCO, PIHP or PAHP. The original heading of § 438.60 was ''Limit on payments to other providers;'' we believe that heading was potentially ambiguous or confusing when paired with the regulatory text as it could be read to treat an MCO, PIHP, or PAHP as a provider. We propose to revise the section heading as ''Prohibition of additional payments for services covered under MCO, PIHP, or PAHP contracts'' to make clear that the capitation payments are to be inclusive of all service and associated administrative costs under such contracts. Within this provision, we propose to add the word ''by'' preceding ''the MCO, PIHP, or PAHP'' so that the term ''provider'' clearly refers to health care professionals contracted with the MCO, PIHP, or PAHP. We have clarified the language that made overly broad references to Title XIX of the Act and this title of the CFR to clarify that such

payments are permitted only when statute and regulation specifically stipulate that the state make those payments directly to a provider. We believe that the exception to this standard has always been limited to cases where other law (statutory or regulatory) explicitly directs the state to make the additional payment to the health care provider and propose to strengthen the language accordingly. Finally, we propose to update the cross-reference for GME payments from its current location at § 438.6(c)(5)(v) to proposed § 438.6(b)(4) to reflect the proposed restructuring of § 438.6 as discussed above in the preamble related to setting actuarially sound capitation rates.

b. Subcontractual Relationships and Delegation (§ 438.230)

We propose to replace the current standards in § 438.230 with clearer expectations for MCOs, PIHPs, or PAHPs that enter into subcontractual relationships and delegate responsibilities under the contract with the State. These expectations are modeled on the MA standards relating to MA organization relationships with first tier, downstream, and related entities at § 422.504(i). The MA framework for the flow of responsibilities and obligations are effective program integrity safeguards that are appropriate for Medicaid managed care programs.

In paragraph (a), we propose to more clearly state when § 438.230 would apply by adding language specifying that the standards of this section would apply to all contracts and written arrangements that a MCO, PIHP, or PAHP has with any individual or entity that relates directly or indirectly to the performance of the MCO's, PIHP's, or PAHP's obligations under the contract.

In a proposed new paragraph (b)(1), we would stipulate that regardless of any relationship that a MCO, PIHP, or PAHP may have, it alone is accountable for complying with all terms of the contract with the state. While this is not a new standard, we believe this revised wording more clearly states our intent. We propose in new paragraph (b)(2) to specify that all contracts and written arrangements comply with the provisions of paragraph (c).

Existing paragraphs (b)(2)(i) (requiring the contract to specify the delegated activities, obligations, and responsibilities) and (b)(2)(ii) (providing for revocation of any delegation) would be redesignated as (c)(1)(i) and (c)(1)(iii) but otherwise remain substantively the same with revisions for clarity. In paragraph (c)(1)(ii), we propose to add that the individual or entity accepting the delegation agrees to perform the activities in compliance with the MCO's, PIHP's, or PAHP's contract with the state. In paragraph (c)(2), we propose a general standard that the entity or individual performing the delegated activities must comply with all applicable laws, regulations, subregulatory guidance, and contract provisions. Lastly, in paragraphs (c)(3)(i) through (iv), we propose that the entity or individual performing the delegated activities must agree to grant the state, CMS, HHS, OIG, or the Comptroller General the right to audit, evaluate, and inspect any books, contracts, computer or other electronic systems that pertain to services performed or determinations of amounts payable; make available for audit, evaluation, or inspection, its premises, physical facilities, equipment and records; preserve the rights under (c)(3)(i) for 10 years from completion; and grant the state, CMS, HHS, or the Comptroller General the right to audit, evaluate, and inspect at any time if the reasonable possibility of fraud is determined to exist by any of these entities.

c. Program Integrity (§ 438.600, § 438.602, § 438.604, § 438.606, § 438.608, and § 438.610)

Current regulatory language implements the provisions of section 1932(d)(1) of the Act regarding MCO and PCCM affiliations with debarred individuals, and addresses certification of data provided by MCOs and PIHPs to the state. Thus, the current regulations related to program integrity are fairly limited in scope. Since the publication of those regulations in 2002, significant new legislative changes have been made to Medicaid program integrity operations. The Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted on February 8, 2006) created the Medicaid Integrity Program (MIP) under section 1936 of the Act. Subsequently, section 6401 of the Affordable Care Act added new sections 1902(a)(77) and 1902(kk)(1) of the Act that require states to comply with the process for screening providers established by the Secretary under section 1866(j)(2) of the Act. Section 6401 of the Affordable Care Act also added a new section 1902(kk)(7) of the Act, which provides that states must enroll all ordering and referring physicians or other professionals as participating providers (and thus screen them according to the aforementioned screening process). We issued final regulations implementing these Affordable Care Act provisions in the February 2, 2011 **Federal Register**, ''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'' (76 FR 5862). However, those regulations specifically exclude from enrollment requirements Medicaid providers that only order or refer services as part of a risk-based managed care plans' network (76 FR 5904). Reasons cited at that time were consistency of treatment between MA organizations and Medicaid managed care plans as well as the administrative burden that enrollment of managed care plans' ordering and referring physicians and other professionals would impose on state Medicaid agencies. In addition to standards established by the Affordable Care Act, section 1902(a)(27) of the Act stipulates that states must enroll ''person(s) or institution(s) providing services under the State plan.'' In the past, we have not interpreted that provision as applying to providers or institutions that furnish state plan services in the managed care context.

Since issuance of the final rule for the aforementioned Affordable Care Act provisions, states, primarily through communications from the National Association of Medicaid Directors (NAMD), have reported that state program integrity reviews have identified as a vulnerability the lack of consistency in the application of the provider screening and enrollment provisions applicable to FFS providers in states' managed care programs. The HHS Office of the Inspector General (OIG) has issued similar findings and recommendations in the reports identified below. Given the growing reliance of states on managed care plans to administer covered benefits, we are concerned that the vulnerability of state and federal Medicaid funds to fraud by network providers will only increase. We therefore, address the provider screening and enrollment processes for network providers in this proposed rule.

In addition, we are taking a broader approach to rethinking Medicaid managed care program integrity provisions. Specifically, we have considered findings from the State Program Integrity Reviews undertaken by CMS through the Center for Program Integrity, as well as recommendations from the OIG to inform our proposals for this subpart and improve managed care program integrity processes. See, for example, OIG, *State and CMS Oversight of the Medicaid Managed Care Credentialing Process* (OEI–09–10–00270) (Nov. 2013), available at *http://oig.hhs.gov/oei/reports/oei-09-10-00270.pdf*; OIG, *Excluded Providers in*

Medicaid Managed Care Entities (OEI–07–09–00630) (Feb. 2012), available at *https://oig.hhs.gov/oei/reports/oei-07-09-00630.pdf*; OIG, *Medicaid Managed Care: Fraud and Abuse Concerns Remain Despite Safeguards* (OEI–01–09–00550) (Dec. 2011), available at *http://oig.hhs.gov/oei/reports/oei-01-09-00550.pdf*. Of particular concern are two types of program integrity risks: Fraud committed by Medicaid managed care health plans and the vulnerability of state and federal Medicaid funds to fraud by network providers. Through the changes proposed in this rule, we intend to address both of these types of risk, as well as tighten standards for MCO, PIHP, PAHP, PCCM, and PCCM entity submission of certified data, information and documentation that is critical to program integrity oversight by state and federal agencies. Our proposal would modify the title of subpart H to ''Additional Program Integrity Safeguards'' from the current title ''Certifications and Program Integrity'' to recognize that various program integrity standards, such as those relating to audited financial data, MLR, and subcontractual relationships, among others, are proposed to be added throughout this part. In addition, we propose to add entirely new provisions and amend existing provisions to address program integrity risks.

(1) Proposed Revisions to § 438.600

In § 438.600, we propose to add to the existing list of statutory provisions related to program integrity that support our proposed changes to this subpart. Our proposal would include the following statutory provisions: Sections 1128, 1128J(d), 1902(a)(4), 1902(a)(19), 1902(a)(27), 1902(a)(68), 1902(a)(77), 1902(a)(80), 1902(kk)(7), 1903(i), 1903(m), and 1932(d)(1) of the Act. In the description of section 1932(d)(1) of the Act in § 438.600, we propose to remove the term ''excluded'' and replace it with ''debarred'' to reflect the statutory standard. As a general matter, we rely on section 1902(a)(4) of the Act when standards in this subpart are proposed to extend beyond MCOs to PIHPs, PAHPs, PCCMs, and PCCM entities.

(2) Proposed Revisions to § 438.602

We propose to replace § 438.602 in its entirety. The current regulation provides a general statement of applicability under this subpart that MCOs, PIHPs, PAHPs, and PCCMs must comply with the program integrity and certification standards of the subpart as a condition of payment. The intent of the revisions to § 438.602 is to contain all state responsibilities associated with program integrity in one section. Proposed paragraph (a) sets forth the state's monitoring standards for contractor compliance with provisions in this subpart and § 438.230 (subcontractual relationships and delegation) and § 438.808 (excluded entities).

In § 438.602(b), we propose that states must enroll all network providers of MCOs, PIHPs, and PAHPs that are not otherwise enrolled with the state to provide services to FFS Medicaid beneficiaries. Such enrollment would include all applicable screening and disclosure standards under part 455, subparts B and E. This standard would ensure that all providers that order, refer or furnish services under the state plan or waiver are appropriately screened and enrolled. We also propose that this standard apply to PCCMs and PCCM entities, to the extent that the primary care case manager is not otherwise enrolled with the state to provide services to FFS Medicaid beneficiaries. Our proposal that states must screen and enroll network providers would not obligate the network provider to also render services to FFS beneficiaries.

This proposal is based on an expanded interpretation of sections 1902(kk)(1) and 1902(kk)(7) and 1902(a)(27) of the Act to apply to providers that order, refer, or furnish services in the context of Medicaid managed care to ensure that there are no 'safe havens' for providers who, though unable to enroll in Medicaid FFS programs, shift participation from managed care plan to managed care plan to avoid detection. We further expect that, absent additional requirements in managed care contracts, this approach will result in administrative and cost efficiencies by eliminating the need for each managed care plan to conduct duplicative screening activities as part of the credentialing process as described in § 438.214 for network providers and having that function performed instead by states (or, in the case of dually-participating providers, by Medicare contractors) for all providers. However, this approach would not prohibit managed care plans from conducting their own additional level of provider screening if so desired or states from incorporating other screening requirements into their contracts. This approach also has the advantage of applying the 'limited,' 'moderate' and 'high' risk provider screening protocols (including site visits for providers in the moderate and high risk categories) to all providers that order, refer, or furnish services to Medicaid beneficiaries, whether through managed care or FFS. We request comment on this approach; in particular, we seek feedback on any barriers to rapid network development that this approach might create by limiting the ability of MCOs, PIHPs, or PAHPs to contract with providers until the results of the state's screening and enrollment process are complete. This proposal does not alter the MCO's, PIHP's, or PAHP's responsibility under § 438.214(c) to operate a provider selection process that does not discriminate against providers that serve high-risk populations or that specialize in costly treatments or the state's responsibility to monitor the implementation of provider selection policies in § 438.214(a).

In paragraph (c), we propose that the state must review the ownership and control disclosures submitted by the, MCO, PIHP, PAHP, PCCM, or PCCM entity, and any subcontractors, in accordance with 42 CFR part 455, subpart B. In paragraph (d), we propose that states must conduct federal database checks, consistent with the standards in 42 CFR 455.436, to confirm the identity of and determine the exclusion status of the MCO, PIHP, PAHP, PCCM, or PCCM entity, any subcontractor, any person with an ownership or control interest, or any agent or managing employee at the time of entering into the contract and no less frequently than monthly thereafter. If a state determines a match, it must promptly notify the MCO, PIHP, PAHP, PCCM, or PCCM entity and take action consistent with proposed § 438.610(c). In paragraph (e), we propose that the state must periodically, but no less frequently than once every 3 years, conduct, or contract for the conduct of, an independent audit of the accuracy, truthfulness, and completeness of the encounter and financial data submitted by, or on behalf of, each MCO, PIHP, and PAHP. In paragraph (f), we propose to incorporate the requirement for states to receive and investigate information from whistleblowers. In paragraph (g), we propose that each state must post on its Web site or otherwise make available, the MCO, PIHP, PAHP, or PCCM entity contract, the data submitted to the state under proposed § 438.604, and the results of any audits conducted under paragraph (e) of this section. We propose to add PCCM entity contracts to this standard as we propose in § 438.3(r) that such contracts be submitted for our review and approval. This proposal is discussed in detail in section I.B.6.e. of this proposed rule. In paragraph (h), we propose that states have conflict of interest safeguards in place consistent with proposed § 438.58. In paragraph (i), we propose that the

state must ensure, consistent with section 1902(a)(80) of the Act, that the MCO, PIHP, PAHP, PCCM, or PCCM entity is not located outside of the United States and that no payments are made for services or items to any entity or financial institution outside of the U.S. We interpret this payment prohibition to mean that no such payments made by an MCO, PIHP, or PAHP to an entity or financial institution located outside of the U.S. are considered in the development of actuarially sound capitation rates.

(3) Proposed Revisions to § 438.604 and § 438.606

We propose to modify existing standards regarding submission and certification of data by managed care plans to the state which currently exist in §§ 438.604 and 438.606. We propose to revise § 438.604(a) and (b) to specify data, information and documentation that must be submitted by each MCO, PIHP, PAHP, PCCM, or PCCM entity to the state, including encounter data and other data generated by the health plan for purposes of rate-setting; data on which the state determined that the entity met the MLR standards; data to ensure solvency standards are met; data to ensure availability and accessibility of services; disclosure information as described at 42 CFR part 455, subpart B; the annual report on recoveries of overpayments as proposed in § 438.608(d)(3); and any other data related to the performance of the entity's obligations as specified by the state or the Secretary. For example, the state or the Secretary could specify that MCOs, PIHP, or PAHPs submit to the state elements of claims from network providers (for example, rendering provider NPI, services dates, place of service, procedure code, etc.) to enable the state to review the claims paid for program integrity purposes. These data submission proposals are tied to the substantive standards on these issues proposed and discussed elsewhere in this proposed rule. We believe it is critical and necessary for the proper and efficient administration of the state plan that key program data submitted by MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities to states is certified as accurate, complete and truthful, as that data will be the basis for any state or federal program integrity reviews. Therefore, the proposed § 438.606 stipulates that MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities must certify the data, information and documentation specified in § 438.604.

Our proposal builds upon existing provisions in § 438.606. We propose to expand the certification requirement to documentation and information as well as data and propose to cross-reference the submission standards in § 438.604 to identify the scope of the certification requirement. Further, we propose to extend the applicability of § 438.606 from MCOs and PIHPs to PAHPs, PCCMs, and PCCM entities, based on our authority under section 1902(a)(4) of the Act to identify and stipulate activities that are necessary for the proper and efficient administration of the state plan. In § 438.606(a), we propose to eliminate the option for a MCO's, PIHP's, PAHP's, PCCM's, or PCCM entity's executive leadership to delegate the certification, since we believe that in these critical program areas, the CEO or CFO must be personally responsible for the accuracy, completeness, and truthfulness of the reported data, documentation or information.

In § 438.606(b), we propose to include documentation or information after the existing reference to data for consistency with the addition of such terms in § 438.604 and § 438.606 and to specify that the certification attests that the MCO, PIHP, PAHP, PCCM, or PCCM entity has conducted a reasonably diligent review of the data, documentation, and information in § 438.604(a) and (b) and that such data, documentation, and information is accurate, complete, and truthful. We propose this modification to the certification to clarify that the attesting individual has an affirmative obligation to ensure that a reasonably diligent review has been conducted and that the information being certified is accurate, complete, and truthful. For a certification to be helpful for program integrity purposes, an individual who is certifying information must make some effort to ensure that the information is accurate. It is not enough to simply believe the information is the best; the individual must make an effort to determine the information is accurate. The proposed clarification to the certification requirement is consistent with other program integrity safeguards in this proposed rule, such as those in § 438.608(a) that include requirements to take affirmative action (for example, routine auditing and monitoring) to detect and prevent fraud, waste, and abuse. For purposes of determining if a ''reasonably diligent'' review has been conducted, we propose to borrow from the standards in the final rule for MA and Part D overpayment rules published in the **Federal Register** on May 23, 2014 (79 FR 29844, 29923). In the preamble for that final rule, we clarified that ''at a minimum, reasonable diligence would include proactive compliance activities conducted in good faith by qualified individuals. However, conducting proactive compliance activities does not mean that the person has satisfied the reasonable diligence standard in all circumstances. In certain circumstances, for example, reasonable diligence might require an investigation conducted in good faith and in a timely manner by qualified individuals . . .'' We request comment on the proposal to clarify the certification standard, including comments on using the existing reasonably diligent review standard from the MA and Part D context.

In paragraph (c), we propose to maintain the existing standard that the certification is provided concurrently with the submission of the data, documentation or information specified in § 438.604.

(4) Proposed Revisions to § 438.608

Current § 438.608 specifies the elements that must be included in a MCO's and PIHP's program integrity/compliance program and administrative procedures to detect and prevent fraud, waste and abuse; we are proposing to expand those standards to PAHPs, and to subcontractors to the extent that the subcontractor is delegated responsibility by the MCO, PIHP, or PAHP for coverage of services and payment of claims under the contract between the State and the MCO, PIHP, or PAHP, to include or redesignate the following:

- Establishment of written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable requirements and standards under the contract, and all applicable Federal and state requirements (propose to redesignate § 438.608(b)(1) as § 438.608(a)(1)(i)).
- Direct reporting by the Compliance Officer to both the CEO and board of directors of the MCO, PIHP, or PAHP, which is consistent with MA requirements at 42 CFR 422.503(b)(4)(vi)(B)(2); the designation of compliance officer that is accountable to senior management is at current § 438.608(b)(2) (proposed § 438.608(a)(1)(ii));
- Establishment of a Regulatory Compliance Committee on the Board of Directors and at the senior management level charged with oversight of the compliance program, which is consistent with MA requirements at 42 CFR 422.502(b)(4)(vi)(B); the establishment of a compliance committee is at current § 438.608(b)(2) (proposed § 438.608(a)(1)(iii));
- Establishment of a system for training and education for the

Compliance Officer, the organization's senior management, and the organization's employees for the federal and state standards and requirements under the contract, which is consistent with MA organization requirements at 42 CFR 422.503(b)(4)(vi)(C); effective training and education for the compliance officer and the organization's employees is at current § 438.608(b)(3) (proposed § 438.608(a)(1)(iv));

- Establishment of a system for effective communication between the compliance officer and the organization's employees (propose to redesignate § 438.608(a)(4) as § 438.608(a)(1)(v));
- Enforcement of standards through well-publicized disciplinary guidelines (propose to redesignate § 438.608(b)(5) as § 438.608(a)(1)(vi));
- Establishment and implementation of procedures and a system with dedicated staff for routine internal monitoring and auditing of compliance risks, prompt response to compliance issues as they are raised, investigation of potential compliance problems as identified in the course of self-evaluation and audits, correction of such problems promptly and thoroughly (or coordination of suspected criminal acts with law enforcement agencies) to reduce the potential for recurrence, and ongoing compliance with the requirements under the contract; the provision for internal monitoring and auditing and prompt response to detected offenses is at current § 438.608(b)(6) and (7) (proposed § 438.608(a)(vii));
- Mandatory reporting to the state of potential fraud and improper payments identified or recovered by managed care plans (proposed § 438.608(a)(2));
- Mandatory reporting to the state of information received by managed care plans about changes in an enrollee's circumstances that may affect the enrollee's eligibility (proposed § 438.608(a)(3));
- Mandatory reporting to the state of information received by the managed care plan about changes in a provider's circumstances that may affect the provider's participation in the managed care program. Such changes in circumstances would include the termination of the provider agreement with the health plan (proposed § 438.608(a)(4));
- Verification by sampling or other methods, whether services that were represented to have been delivered by network providers were actually received (proposed § 438.608(a)(5));
- Establishment of written policies related to the Federal False Claims Act, including information about rights of employees to be protected as whistleblowers (proposed § 438.608(a)(6));
- Mandatory referral of any potential fraud, waste, or abuse that the MCO, PIHP, or PAHP identifies to the State Medicaid program integrity unit or any potential fraud directly to the State Medicaid Fraud Control Unit (proposed § 438.608(a)(7)). States that have a Medicaid Fraud Control Unit (MFCU) may choose, as part of their contracts with MCOs, PIHPs, or PAHPs, to stipulate that suspected provider fraud be referred only to the MFCU, to both the MFCU and to the Medicaid program integrity unit, or only to the Medicaid program integrity unit. For those matters referred to the Medicaid program integrity unit, 42 CFR part 455 provides that the unit must conduct a preliminary investigate and cooperate with the MFCU in determining whether there is a credible allegation of fraud. For those MCOs, PIHPs, and PAHPs with their own Special Investigation Unit (SIU) to investigate suspected provider fraud, the program integrity unit should assess the adequacy of the preliminary investigation conducted by those units and seek to avoid the duplication and delay of their own preliminary investigation.
- Provision for the MCO's, PIHP's, or PAHP's suspension of payments to a network provider for which the state determines there is a credible allegation of fraud in accordance with § 455.23 (proposed § 438.608(a)(8)). Under § 455.23, which implements section 1903(i)(2)(C) of the Act, the state must suspend payments to an individual or entity against which there is a pending investigation or a credible allegation of fraud against the individual or entity, unless the state determines that there is good cause not to suspend such payments. We note that the state's obligation to suspend payments is not limited to FFS payments. In the final rule for the suspension of payment provisions (76 FR 5862, 5938), we discussed the applicability of the suspension of payment requirements to Medicaid managed care plans. We stated that ''if there is a pending investigation of a credible allegation of fraud against a Medicaid MCO, PIHP, or PAHP, the state should address the issue either through imposing a payment suspension or through other authorities that may be available to them under state law or as part of the state's negotiated agreement with the Medicaid MCO, PIHP, or PAHP. The same would hold true for pending investigations of credible allegations of fraud regarding individual network providers. Managed care capitation payments may be included in a suspension when an individual network provider is under investigation based upon credible allegations of fraud.'' Since the publication of the final rule it has become clear that suspension of capitation payments to MCOs, PIHPs, or PAHPs is not the most effective means of suspending payments to individual network providers who are subject to pending investigations for credible allegations of fraud. Accordingly, under our authority in sections 1903(i)(2)(C) and 1902(a)(4) of the Act, we propose to require that the state make provision for the MCO, PIHP, or PAHP to suspend payment to a network provider when the state determines there is a credible allegation of fraud, unless the state determines there is good cause for not suspending payments to the network provider pending the investigation. This will enable states to carry out section 1903(i)(2)(C) of the Act and safeguard federal Medicaid funds by not making payments to network providers under investigation for credible allegations of fraud, whether those providers are participating in Medicaid FFS or in Medicaid managed care networks. Under this provision, the responsibility of MCOs, PIHPs, and PAHPs would be limited to promptly suspending payments at the direction of the state until notified by the state that the investigation has concluded.

These additional elements of a MCO's, PIHP's, or PAHP's program integrity program have been recommended by CMS and OIG reports or, in the case of eligibility information, address any identified gap in information flow from MCOs, PIHPs, or PAHPs to the state about enrollees.

As part of the compliance program, we propose in § 438.608(a)(1)(vi) that the MCO, PIHP, or PAHP establish procedures and a system, including dedicated staff, for promptly responding to compliance issues, including possible criminal acts such as provider fraud. Many MCOs, PIHPs, and PAHPs employ a SIU to specifically focus on suspected provider fraud and to coordinate with State program integrity officials and law enforcement agencies, such as the state MFCU. A managed care plan's coordination with law enforcement to ensure the effective investigation of fraud, waste, and abuse is a vital component of a successful program integrity program. As part of their coordination with law enforcement, MCOs, PIHPs, and PAHPs should adopt policies and procedures that ensure information exchange between the managed care plans, the state, and law enforcement so that all stakeholders can

be aware of fraud trends across their respective geographic areas. In addition, effective coordination between MCOs, PIHPs, and PAHPs with law enforcement and the state will ensure that the state meets its program integrity obligations under 42 CFR part 455 and the provisions of this part.

Proposed § 438.608(b) incorporates the provider screening and enrollment standards in § 438.602(b).

In paragraph (c) of § 438.608, we propose additional expectations for performance by managed care plans that the state must include in their contracts, including:

- Requiring MCOs, PIHPs, and PAHPs to disclose in writing any prohibited affiliation outlined in § 438.610 (proposed paragraph (c)(1));
- Requiring written disclosures of information on control and ownership under § 455.104 (proposed paragraph (c)(2)); and
- Requiring MCOs, PIHPs, and PAHPs to report to the state within 60 calendar days of when they identify receipt of payments in excess of the capitation rate or other payments established in the contract. For example, the state may remit payment to the MCO, PIHP, or PAHP in accordance with an erroneous number of member months and such overpayments should be a matter for prompt disclosure and remediation by the state. Other payments under the contract would be kick-payments for high cost services that were not delivered or amounts received under incentive or withhold arrangements (as proposed in § 438.6(a) and (b)) for which the MCO, PIHP, or PAHP did not satisfy the performance criteria under the arrangement (proposed paragraph (c)(3)).

We request comment on whether we should establish timeframes for the disclosures proposed in this section to be provided to the state.

In § 438.608(d)(1), we propose that MCO, PIHP, and PAHP contracts specify that recoveries of overpayments made by the MCO, PIHP, or PAHP to providers that were excluded from Medicaid participation or that were due to fraud, waste or abuse are to be retained by the MCO, PIHP, or PAHP. Because these overpayments represent state and federal Medicaid funds that were paid to the excluded or fraudulent providers by the MCO, PIHP, or PAHP, states are then expected to take such recoveries into account in the development of future actuarially sound capitation rates as proposed in § 438.608(d)(4). This approach is similar to that taken by CMS in addressing provider recoveries in the MA program; in that program, encounter data that reflects services paid to excluded providers or other variations of provider fraud are excluded from consideration for future rate development. This has been an area of confusion for both states and health plans, since federal statute and regulations do not currently specify who may retain MCO, PIHP, or PAHP recoveries. In addition, we believe that the retention of recoveries made by the managed care plan further supports the overall program integrity oversight and monitoring framework for managed care plans proposed in § 438.608. The proposal in § 438.608(d) does not prohibit the federal government or states from retaining the appropriate share of recoveries of overpayments due to their own audits and investigation. We solicit comment on this proposal to allow MCOs, PIHPs, and PAHPs to retain overpayment recoveries of payments made to providers that were excluded from Medicaid participation or that were due to fraud, waste or abuse that were made by the managed care plan, while also allowing the federal government and states retain overpayment recoveries they make. We also request comment on alternative approaches to determining when a recovery may be retained by an MCO, PIHP, or PAHP. Specifically, whether we should instead impose a timeframe between 6 months to 1 year for which the MCO, PIHP, or PAHP may act to initiate the recovery process and retain such recovered overpayments. We further propose that, consistent with that contractual language, the state collect reports from each MCO, PIHP, or PAHP about recoveries of overpayments in proposed § 438.608(d)(3). To aid in the creation and submission of such reports in proposed paragraph (d)(3), in paragraph (d)(2) we propose a standard that the MCO, PIHP, or PAHP must have a mechanism in place for network providers to report the receipt of overpayments and to return such overpayments to the MCO, PIHP, or PAHP within 60 calendar days after the overpayment was identified. For clarity, in proposed (d)(5) we define the term ''overpayment.''

(5) Proposed Revisions to § 438.610

We propose to revise the title of § 438.610 from ''Prohibited affiliations with individuals debarred by federal agencies'' to ''Prohibited affiliations.'' This proposed change is in recognition of the addition of individuals or entities excluded from Medicaid participation under section 1128 of the Act. The current title also did not adequately reflect the proposed scope of this section as it did not include ''entities.'' In paragraph (a), which provides the general standards under this section, we have added PCCM and PCCM entities through our authority for the proper and efficient administration of the state plan in section 1902(a)(4) of the Act. In paragraphs (a)(1) and (a)(2) that specify the types of knowing relationships in section 1932(d)(1)(C) of the Act, we propose to clarify that these relationships may be with individuals or entities that meet those criteria. The existing language refers only to individuals and the proposed addition is consistent with the definition of ''persons'' in the Federal Acquisition Regulation and the Nonprocurement Common Rule. In addition, we propose to add paragraph (b) to include individuals or entities excluded from Medicaid participation under section 1128 or 1128A of the Act in the list of prohibited relationships by the MCO, PIHP, PAHP, PCCM, or PCCM entity, as specified in section 1902(p)(2) of the Act. We note that in the case of excluded individuals and entities, the prohibition applies whether or not the relationship is known to the MCO, PIHP, PAHP, PCCM, or PCCM entity. We propose to redesignate paragraph (b) that specifies the relationships that are prohibited as paragraph (c) to accommodate the proposed inclusion of individuals or entities excluded from participation under section 1128 of the Act. In addition, we propose to add subcontractors of the MCO, PIHP, PAHP, PCCM, or PCCM entity as described in § 438.230 to the types of prohibited relationships in paragraph (c)(3). In paragraph (c)(4), we propose to add network providers to clarify that they fall under the employment or other consulting arrangement for items and services under the contract between the state and the managed care plan. Due to the proposed restructuring of paragraphs within this section, we propose to redesignate paragraph (c) as paragraph (d) without change, with the exception of those described below. In paragraph (d)(3), we propose to clarify that the compelling reasons for continuation of a managed care plan's agreement with a prohibited individual or entity must be so despite the prohibited affiliation. In addition, we propose a new paragraph (d)(4) to clarify that this section does not limit or affect any remedies available to the federal government under sections 1128, 1128A or 1128B of the Act. Finally, we propose to redesignate paragraph (d) as paragraph (e) without change.

d. Sanctions (§ 438.700, § 438.702, § 438.704, § 438.706, § 438.708, § 438.722, and § 438.730)

Throughout subpart I pertaining to sanctions, we propose to extend standards applicable to PCCMs to PCCM entities, as we propose to recognize PCCM entities as a type of primary care case manager as defined in section 1905(t)(2) and referenced in section 1932(a)(1)(B)(ii) of the Act. The discussion of the proposed recognition and application of standards in this part to PCCM entities is described in section I.B.6.e. of this proposed rule. Therefore, we propose to add PCCM entities to § 438.700(a), (c), and (d)(2); § 438.704(a), § 438.708, and § 438.722.

In § 438.700(a), we propose to clarify that the intermediate sanctions specified in § 438.702 ''may'' be used by the state, rather than providing that these ''must'' be the sanctions that the state establishes. The current regulation could be interpreted to mean that the specific intermediate sanctions enumerated must be used by the state, even though section 1932(e)(1) of the Act only stipulates that intermediate sanctions be in place for the specified violations, and that such intermediate sanctions may include those specified in section 1932(e)(2) and set forth in § 438.702. The standard in section 1932(e)(1) of the Act that is a condition for having or renewing a MCO contract is only that there be intermediate sanctions in place.

In § 438.700(c), we propose to delete PIHPs and PAHPs from the state's determination that unapproved or misleading marketing materials have been distributed as provided for in the last sentence of section 1932(e)(1) of the Act. In the 2002 final rule, we included PIHPs and PAHPs in the regulation text implementing this sentence but have determined that this provision, by its terms only applies to a ''managed care entity.'' While a PCCM may be both a managed care entity and a PAHP, if it is paid on a risk basis, it would only be subject to this provision based on its managed care entity status, and not based on its status as a PAHP. In this paragraph, we propose to add PCCM entities consistent with the discussion of PCCM entities in the opening paragraph of this section of this proposed rule, and with the fact that the definition of managed care entity includes a PCCM.

In § 438.702(a)(4), we propose to delete the phrase ''after the effective date of the sanction,'' and insert ''after the date the Secretary or the State notifies the MCO or PCCM of a determination of a violation of any standard under sections 1903(m) or 1932 of the Act.'' The proposed language is identical to the statutory standard in section 1932(e)(2)D) of the Act and we believe that the current language did not fully reflect the statutory directive.

Currently, § 438.706 discusses special rules for temporary management and, in paragraph (a), we reference ''onsite survey, enrollee complaints, financial audits, or any other means'' as acceptable ways to determine if an MCO must be subjected to temporary management. However, this language is inconsistent with language at § 438.700(a) that references ''onsite surveys, enrollee or other complaints, financial status, or any other source'' as a means to determine imposable sanctions. We propose to correct this inconsistency by revising § 438.706(a) to incorporate the language of § 438.700(a).

In § 438.724(a), we propose to delete the reference to ''Regional Office,'' consistent with proposed changes in § 438.3(a) and § 438.7(a).

Section 438.730 currently addresses sanctions imposed by us on MCOs and paragraphs (e)(1) and (e)(2) use the term ''HMO.'' The Balanced Budget Act of 1997 (BBA) replaced the term ''Health Maintenance Organization (HMO)'' with ''Managed Care Organization (MCO).'' We propose to correct these obsolete references to HMO in paragraphs (e)(1) and (2) by replacing the term with ''MCO.'' In addition, current § 438.730 uses ''State agency'' or ''agency,'' which is inconsistent with references to the state in subpart H as well as our proposal to create a uniform definition for ''state'' in § 438.2. We therefore propose revisions to address this.

We also propose to correct several inaccurate cross-references to other provisions of the regulations text. In § 438.730(f)(1), the reference to ''paragraph (b)'' would be revised to reference ''paragraph (c).'' In § 438.730(f)(2)(i) and (ii), the reference to ''(d)(2)(ii)'' would be revised to reference ''(d)(2)'' and the reference to ''(c)(1)(ii)'' would be revised to reference ''(d)(1)(ii).'' Finally, in § 438.730(g)(1), the reference to ''paragraph (c)(1)(i)'' would be revised to reference ''paragraph (c)(1).''

e. Deferral and/or Disallowance of FFP for Non-Compliance With Federal Standards (§ 438.807)

We propose to add a new § 438.807 to specify that we may defer and/or disallow FFP for expenditures under a MCO contract identified in section 1903(m)(2)(A) of the Act when the state's contract, as submitted for our approval or as administered, is non-compliant with standards therein, with section 1932 of the Act, or with the provisions of 42 CFR part 438 implementing such standards. These standards include whether final capitation rates, as specified in the contract and detailed in the rate certification, are consistent with the standards of actuarial soundness proposed in §§ 438.4 through 438.7. The proposed process for issuance of a deferral or a disallowance is the same as the process identified in § 430.40 and § 430.42, respectively.

Section 1903(m)(2)(A) of the Act specifies that if the requirements set forth in paragraphs (i) through (xiii) therein are not satisfied, no federal financial participation (FFP) is authorized for expenditures incurred by the state for services under a prepaid capitation or other risk-based contract under which the payment is for inpatient hospital services and any other service described in paragraph (2), (3), (4), (5), or (7) of section 1905(a), or for the provision of any three or more of the services described in such paragraphs. We have previously interpreted this to mean that if the state fails to comply with any of the listed conditions, there could be no FFP at all for payments under the contract, even for amounts associated with services for which there was full compliance with all requirements of section 1903(m)(2)(A) of the Act. This interpretation has resulted in a potential penalty that in some cases would be out of proportion to the nature of the violation, under which FFP would be withheld for payment amounts representing services which are in compliance.

We interpret section 1903(m)(2)(A) of the Act that the enumerated services are for purposes of defining the minimum scope of covered services under a comprehensive risk, or MCO, contract. We propose that deferrals and/or disallowances of FFP can be targeted to all services under the MCO contract even if not listed explicitly in section 1903(m)(2)(A), rather than FFP in the full payment amount made under the contract. Specifically, we are proposing in § 438.807 to interpret section 1903(m)(2)(A) of the Act to condition FFP in contract payment amounts on a service by service basis, so that, for example, if the violation involved the payment amount associated with coverage of inpatient hospital costs and that is the only portion of the payment amount that is not actuarially sound, then FFP in only that portion of the payment would be deferred or disallowed. This approach is supported by an interpretation of section

1903(m)(2)(A) of the Act that the phrase ''no payment shall be made under this title to a State with respect to expenditures incurred by it for payment . . . for services provided by any entity'' is read to place the emphasis on ''payment for services provided by any entity'' without regard to what the services are, so long as the minimum scope of covered services for a MCO contract is satisfied. Under our proposal, we would be able to defer and/or disallow partial FFP under the contract associated with only a particular service category if a violation involves only that category of services and not the delivery of services generally. Such determinations may be made prospectively, for example, when the contract or rate certification is submitted for CMS' review and approval, or on a retroactive basis based on how the contract is operationalized or if it is determined through audit that the rate development standards supporting the rate certification were not compliant with the requirements proposed in this part. We believe that this proposal would result in a more fair and measured penalties for violations, and lead to more expedient resolution of compliance actions.

The deferral of FFP would be taken against the state's request for grant awards attributed to managed care contracts on the CMS–37. States must request the grant award 45 days prior to the start of the quarter. The CMS–64, which reconciles the amount of the grant award to actual expenditures, is due within 30 days of the expiration of the quarter. The timeframe for the CMS–64 submission overlaps with the timeframe for the grant request on the CMS–37 for the next quarter. We provide the following example to illustrate when the deferral would be applied for a noncompliant contract effective on January 1. The state would have included the expenditures under the managed care contract on the CMS–37 no later than November 15. In the interim, we would conduct a review of the contract and rate certifications and identify any compliance issues. The state submits the CMS–64 for the first quarter of the calendar year by April 30, and the CMS–37 grant request for the second quarter was submitted by February 15. Assuming that CMS and the state were unable to resolve the compliance issue according to the process set forth in the regulation, we would assess the deferral of FFP against the CMS–37 request for the third quarter of the calendar year in a proportionate amount of the contract rate that reflects the non-compliant activity. We seek comment on these proposals.

f. Exclusion of Entities

Section 438.808 implements the requirements in section 1902(p)(2) of the Act for the types of organizations or entities that the state must not contract with in order for the state to receive federal payments for medical assistance. The existing regulation in paragraph (a) includes MCOs but does not incorporate the statutory directive in section 1902(p)(2) of the Act to similarly exclude ''an entity furnishing services under a waiver approved under section 1915(b)(1)'' that would fall under the entities that must be excluded in paragraph (b) of this section. We propose to include such entities in paragraph (a) to clarify that PIHPs, PAHPs, PCCMs or PCCM entities that have contracts with the state under a section 1915(b)(1) waiver would also be subject to the this provision. There is no requirement in the statute that MCO contracts be tied to a specific managed care authority so we propose that all MCO contracts under any authority be subject to this provision.

5. Beneficiary Protections

a. Enrollment (§ 438.54)

In this section we address a gap in the current managed care regulations regarding the enrollment process. Other than the default enrollment standards currently in § 438.50(e) and (f) for MCOs and PCCMs, there are no federal regulations governing enrollment of beneficiaries into managed care programs. In the absence of specific federal regulatory provisions, states have used a number of different approaches to enrolling beneficiaries into voluntary and mandatory managed care programs. The variation in proposed processes revealed a need for guidance to ensure an appropriate, minimum level of beneficiary protection and consistency across programs. In this section, we propose basic federal standards for enrollment while continuing to permit state flexibility in designing enrollment processes for Medicaid managed care programs.

Among states currently operating voluntary Medicaid managed care programs, which allow each beneficiary to choose to receive services through either a managed care or FFS delivery system, states have generally used a passive enrollment process to assign a beneficiary to a managed care plan immediately upon being determined eligible. Typically, the beneficiary is provided a period of time to elect to opt-out of enrollment from the state-assigned managed care plan and select a different managed care plan or elect to opt-out of managed care completely and, instead, receive services through a FFS delivery system. If the beneficiary does not make an affirmative choice, the beneficiary remains enrolled in the state-assigned managed care plan during the period of Medicaid eligibility and enrollment. Our experience shows the rate of potential enrollees that opt-out is generally very low.

In a mandatory Medicaid managed care program, beneficiaries must receive Medicaid benefits from managed care plans. Under section 1932(a)(4)(A)(ii)(I) of the Act, beneficiaries in a mandatory managed care program have the right to change plans without cause within 90 days of enrolling in the plan and every 12 months; enrollees may also change plans for cause at any time. When the beneficiary does not actively select a managed care plan in the timeframe permitted by the state, states have generally used the default assignment process to assign individuals into plans. Section 1932(a)(4)(D) of the Act and current implementing regulations at § 438.50(f) outline the process that states must follow to implement default enrollment (also commonly known as auto-assignment) in a mandatory managed care program.

In both voluntary and mandatory managed care programs, we believe that beneficiaries are best served when they affirmatively exercise their right to make a choice of delivery system or plan enrollment. Optimally, this involves both an active exercise of choice and requisite time and information to make an informed choice. Given the sensitive nature of this transition from FFS to managed care or from one managed care system to a new managed care system and the often complex medical, physical and/or cognitive needs of Medicaid beneficiaries, we believe that enrollment processes should be structured to ensure that the beneficiary has an opportunity to make an informed choice of managed care plan and that state processes support a seamless transition for an enrollee to managed care.

Our goal of alignment prompted us to consider how enrollment is conducted in the commercial market and in other public programs. We note that MA is a voluntary managed care program, in which beneficiaries actively select the MA organization during the annual open enrollment period with limited exceptions for passive enrollment. A quarter of all Medicare beneficiaries (approximately 14 million in 2013) are enrolled in MA organizations; of that

number, 1.6 million are enrolled in special needs plans.[11]

To promote integration of care for dually eligible (Medicare and Medicaid) beneficiaries, the section 1115A demonstrations under the capitated financial alignment model operated by the Medicare-Medicaid Coordination Office (MMCO) are using a form of passive enrollment. The enrollment processes generally require notifying dually eligible individuals that they can select a Medicare plan 2 months before they would be enrolled in the plan, but if no active choice is made, enrollment into the plan identified through the passive process takes effect.

We note that some states have re-examined their Medicaid managed care enrollment processes due to an interest in alignment with Marketplace enrollment procedures. Enrollment into a QHP in either the FFM or SBM requires an active selection of a health plan, and in some cases premium payment. Consequently, the online application for the FFM at Healthcare.gov provides the option to select a QHP at the time of application. The FFM single, streamlined application requires follow-up by the individual to enroll in a QHP. SBMs, as well as Medicaid and CHIP agencies, are permitted to develop an alternative single, streamlined application that must be approved by CMS. A few states with mandatory Medicaid managed care programs have included a section in their alternative benefit application that requires applicants to select a Medicaid managed care plan at the time of application. While this approach aligns the processes for Medicaid, CHIP and QHPs, it also eliminates the traditional approach of providing a choice period to select a managed care plan for Medicaid beneficiaries already eligible for FFS coverage.

We are proposing a new § 438.54 to apply a consistent standard for all managed care enrollment processes. At the same time, we are proposing to move and revise, as noted below, the existing provisions in § 438.50(e) and (f) to our new § 438.54. Under these proposed changes, states would implement a set of enrollment standards that are consistent with section 1932(a)(4) of the Act and that promote high quality managed care programs. The goals of this approach are to promote accurate and timely information to beneficiaries about their managed care options; to enable and encourage active beneficiary choice periods for enrollment; and to assure the state's ability to conduct intelligent default enrollments into a managed care plan when necessary.

Through the changes discussed below, we propose to set broad parameters for a state's enrollment process rather than dictate specific elements. In paragraph § 438.54(a) we propose to clarify that the provisions of this section apply to all authorities under which a state may enroll beneficiaries into a managed care delivery system to ensure a broad and consistent application. We note that this includes voluntary managed care programs under section 1915(a) of the Act, as well as mandatory or voluntary programs under sections 1932(a), 1915(b) or 1115(a) of the Act.

We propose in paragraph (b) that the state have an enrollment system for both voluntary and mandatory managed care programs, and propose definitions for those programs, respectively, in paragraphs (b)(1) and (b)(2). These proposals support clarity and consistency.

Proposed paragraph (c) specifies the standards for programs using a voluntary managed care program. In (c)(1), we propose that the state may use either an enrollment system that provides the beneficiary time to make an affirmative election to receive services through a managed care or FFS delivery system or a passive enrollment process. We propose to define a passive enrollment process as one in which the State selects a MCO, PIHP, PAHP, PCCM, or PCCM entity for a potential enrollee but provides a period of time for the potential enrollee to decline the managed care plan selection before enrollment. Using either option, the state must comply with the standards proposed in paragraphs (c)(2) through (c)(8).

In paragraph (d), we propose to set forth standards for enrollment systems for mandatory managed care programs. In (d)(1), we propose that such a system must meet certain standards, listed in proposed paragraphs (d)(2) through (d)(7). We discuss the remaining proposals for (c) and (d) together below as these proposed standards are substantially similar.

In paragraph (c)(2) and (d)(2), we propose a specific enrollment standard applicable to both voluntary and mandatory managed care programs that all states must provide a period of time of at least 14 calendar days of FFS coverage for potential enrollees to make an active choice of their managed care plan. We acknowledge that this 14-day choice period would not be necessary in mandatory programs when there is only one contracted managed care plan within a service area as permitted in § 438.52(b) for rural areas or through a specific authority within a section 1115(a) demonstration program. We believe this minimum time period is important since, similar to enrollees in a commercial insurance product, Medicaid enrollees can be 'locked in' to their selected health plan for up to 1 year. This minimum 14-calendar day period would have to occur between the date that the notice specified in (c)(3) and (d)(3) is sent and the date on which the enrollee becomes covered under the applicable managed care entity. We propose to clarify in (c)(2)(i), that if the state does not use a passive enrollment process and the potential enrollee does not make a choice, then the potential enrollee is enrolled into a managed care plan selected by the state's default process when the choice period has ended. In proposed (c)(2)(ii), we clarify that if the state does use a passive enrollment process and the potential enrollee does not make a choice, then the potential enrollee is enrolled into the managed care plan selected by the state's passive enrollment process when the choice period has ended. In the mandatory program, the minimum 14-day period would have to occur before any default enrollment process is used. However, we are not proposing any passive enrollment mechanism for mandatory managed care programs because the default enrollment mechanism provides the same measure of administrative flexibility. We believe that 2 weeks is sufficient time given that, elsewhere in this proposed rule, we are encouraging states to move to more rapid methods of communicating with enrollees. While we are proposing to require a minimum of 14 days for the choice period, we understand that the state may end the choice period when the potential enrollee actively makes a plan selection prior to the 14th day.

We appreciate that states may want to effectuate managed care enrollment in mandatory programs as soon as possible after eligibility determination, and recognize that providing a minimum active choice period will be a change in process for some states. States would need to provide a period of FFS coverage for beneficiaries between their date of eligibility and their date of managed care enrollment. To minimize any further delay in managed care enrollment, we would allow states to operationalize the 14-day active choice period by advising beneficiaries of the managed care plan they will be enrolled into through the default process if they

[11] Kaiser Family Foundation Medicare Advantage Fact Sheet (*http://kff.org/medicare/fact-sheet/medicare-advantage-fact-sheet/*), accessed April 15, 2014.

do not make an active choice of managed care plan in that 14-day period. According to this process, states would complete the default enrollment process outlined in § 438.54(d)(5) prior to beginning the notice and education process described in paragraph (d)(3) with beneficiaries, and ensure that adequate and appropriate information is provided to beneficiaries regarding the implications of not making an active managed care plan selection. It also enables beneficiaries to override default enrollments by exercising their ability to make an active choice of health plan.

We request comment on the impact of this new standard on managed care program costs and operations, as well as the operational flexibility we are providing to relieve beneficiaries of the burden of receiving too many mailings, which can create confusion, before making the default enrollment permitted in § 438.54. We also invite comment on whether a 14-day period is necessary, provides sufficient time for beneficiaries to make an election, or whether a longer minimum period, such as 30 days or 45 days, should be adopted.

We note that all beneficiaries, regardless of whether enrollment is mandatory or voluntary, must be given the information, education, and opportunity to participate actively in their choice of managed care plan. Paragraphs (c)(3) and (d)(3) propose that states develop informational notices to clearly explain to the potential enrollee the implications of not actively making the decisions available to them and allowing the passive or default enrollment to take effect. Proposed (c)(3)(i) and (d)(3)(i) would provide that the notices comply with § 438.10 and proposed (c)(3)(ii) and (d)(3)(ii) would provide that the notices have a postmark or electronic date stamp that is at least 3 calendar days prior to the first day of the 14-day choice period. We believe this provides reasonable time for either postal delivery or the potential enrollee to read the electronic communication and still have 14 days to make an active selection.

Priority for enrollment into a managed care plan is currently in § 438.50(e); however, for better organization, the text is being deleted from § 438.50 and is proposed as (c)(4) and (d)(4). No other changes are proposed to this text.

We propose in paragraphs (c)(5) and (d)(5) that states assign potential enrollees only to a qualified MCO, PIHP, PAHP, PCCM, or PCCM entity. This concept is currently addressed in § 438.50(f)(2) but only to the extent of excluding those MCOs and PCCMs that are subject to the intermediate sanction in § 438.702(a)(4). In proposed (c)(5)(i) and (d)(5)(i), we propose to exclude MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities subject to sanction under § 438.702(a)(4) and to add paragraph (c)(5)(ii) and (d)(5)(ii) to ensure that a qualified MCO, PIHP, PAHP, PCCM, or PCCM entity has the capacity for new enrollments.

In proposed paragraphs (c)(6) and (d)(6), we address standards that are currently reflected in § 438.50(f) which provides that states have a default enrollment process for assigning a MCO or PCCM when the potential enrollee does not make an active managed care plan selection. As defined in statute, section 1932(a)(4)(D) of the Act provides that a state conduct such enrollments in a manner that takes existing provider-individual relationships into consideration, and if that approach is not possible, to equitably distribute individuals among the participating health plans. While the 2002 final rule strictly interpreted the provisions of section 1932(a)(4)(D) of the Act regarding default enrollment to apply only to enrollment that occurred under state plan authority in section 1932(a) of the Act, we believe that the enrollment processes currently specified in § 438.50(e) and (f) should not be limited only to entities subject to section 1932(a)(4)(D). Allowing potential enrollees sufficient time to make informed decisions about their managed care plan is an important protection that should not exclude potential enrollees of PIHPs and PAHP as well all those subject to voluntary programs that utilize a passive process. Therefore, we propose to make these provisions applicable to all managed care authorities and to both passive and default processes. We add existing text from § 438.50(f)(2) through (f)(4) in proposed paragraphs (c)(6) and (d)(6). While § 438.50(f) currently only applies to default enrollment in mandatory managed care programs, we believe that enrollees in voluntary programs that utilize a passive enrollment process should also benefit from being assigned to a plan based on existing provider relationships or other criteria relevant to beneficiary experience. Therefore, we propose to add standards in (c)(6) for voluntary programs that mirror the standards for mandatory programs using default enrollments.

In proposed paragraphs (c)(7) and (d)(7), we set forth provisions from existing § 438.50(f)(2) that provide that if a state cannot preserve existing provider-beneficiary relationships and relationships with providers that traditionally serve Medicaid, then enrollees must be equitably distributed. Proposed paragraphs (c)(7)(i) and (d)(7)(i) set forth a standard that states may not arbitrarily exclude a MCO, PIHP, PAHP, PCCM, or PCCM entity from the assignment process. We interpret ''equitable distribution'' in section 1932(a)(4)(D)(ii)(II) of the Act to mean not only that the criteria applied to make default enrollments are fair and reasonable, but that the pool of contractors eligible to receive default enrollments is not based on arbitrary criteria. Section 438.50(f) in the 2002 final rule implemented this statutory provision verbatim, but in response to comments on this provision, we clarified that ''states must have the flexibility to consider other factors in the design of a default enrollment process that best meets the needs of the individual,'' *(*67 FR 41020, June 14, 2002). We believe that the flexibility to use additional criteria related to the beneficiary when making default assignments, such as the geographic location of the beneficiary, enrollment preferences of family members, previous plan assignment of the beneficiary, quality assurance and improvement performance, procurement evaluation elements, and other reasonable criteria that support the goal of the Medicaid program, should be provided for in the regulation. Further, we believe that such criteria can be part of an equitable distribution by ensuring fair treatment for enrollees and managed care plans. We note that, an informal survey of state default enrollment practices revealed that some states currently utilize such criteria in their default enrollment process.

For voluntary programs only that use passive enrollment, paragraph (c)(8) proposes that states send confirmation notices to enrollees of their plan selection that contain information explaining the enrollee's right to disenroll from that MCO, PIHP, PAHP, PCCM, or PCCM entity within 90 days. We note that many states use a voluntary model when first starting to introduce managed care, which means the beneficiaries are not as familiar with the limitations of managed care plan enrollment. This additional confirmation notice may help limit unintended plan selections before they take effect.

b. Disenrollment Standards and Limitations (§ 438.56)

We propose to retain the majority of the regulation text currently in § 438.56, with four substantive exceptions:

- We propose, as discussed in more detail in section I.B.5.e. of this proposed rule, to add references to ''PCCM entity'' as applicable;

• We propose to revise the text in paragraph (c)(2)(i) concerning the start of the statutorily mandated 90-day period during which an enrollee may disenroll without cause;

• We propose to explicitly provide that a state may impose either oral or written requests for disenrollment; and

• We propose in (d)(2)(iv) to specify an additional cause for disenrollment. We also propose grammatical and clarifying corrections to the regulation text.

Paragraphs (a) through (c)(1) are unchanged except for the addition of PCCM entity. In paragraph (c)(2)(i), we propose to modify our approach to an enrollee's 90-day without cause disenrollment period. Section 1932(a)(4)(A) of the Act specifies that a state plan must permit disenrollment without cause from a managed care entity during the first 90 days of enrollment under mandatory managed care programs. As part of the 2002 final rule, we exercised authority under section 1902(a)(4) of the Act to extend this standard to state plans with voluntary managed care programs and to PIHPs and PAHPs (whether voluntary or mandatory). As finalized in 2002, we interpreted the clause ''90 days following the date of the beneficiary's initial enrollment'' to mean enrollment with a particular MCO, PIHP, PAHP, or PCCM. That interpretation was intended to allow an enrollee to disenroll from a MCO, PIHP, PAHP, or PCCM every 90 days until he or she had exhausted all contracted MCO, PIHP, PAHP, or PCCM options for which he or she is eligible. We believe that this provision has been applied in an inconsistent manner, and that such an approach is disruptive to the goals of establishing enrollee-provider relationships that support a coordinated delivery system and contribute to medical and administrative inefficiencies. We propose in paragraph (c)(2)(i) to revise the regulation to limit the 90-day without cause disenrollment period to the first 90 days of an enrollee's *initial* enrollment into any MCO, PIHP, PAHP, or PCCM offered through the state plan; therefore, an enrollee would have only one 90-day without cause disenrollment per enrollment period. We believe that the revised approach is consistent with the intent of section 1932(a)(4)(A)(ii) of the Act, represents current practice in the states, and supports efficiency under the Medicaid program. We propose no changes to paragraphs (c)(2)(ii) through (iv).

We propose to add the phrase ''as required by the state'' to § 438.56(d)(1) to clarify that this section of the regulation was intended to give states the flexibility to accept disenrollment requests either orally, or in written form, or both ways if the state so desires. We intend to interpret ''written request'' for purposes of this regulation to include online transactions or requests conducted with an electronic signature. A state could also accept requests orally, but require written confirmation of the oral request. Under our proposal, the state's standard for the form of disenrollment requests would have to be clearly communicated to enrollees to take advantage of this flexibility.

We propose two minor grammatical corrections to paragraph (d) of this section. In paragraph (d)(1)(ii), the term ''PIHP'' is in its singular form, but must be changed to plural to conform to other terms in the paragraph. We also propose to use the possessive form for MCO, PIHP, and PAHP where applicable. In paragraph (d)(2)(iv), we propose to add a new cause for disenrollment: The exit of a residential, institutional, or employment supports provider from an enrollee's MCO, PIHP, or PAHP network. Provider network changes can have a significant impact on those enrolled in MLTSS programs, since such providers are typically integral to residential and work services and supports. Therefore, if the state does not permit participants enrolled in MLTSS to switch managed care plans (or disenroll to FFS), at any time, states must permit enrollees to disenroll and switch to another managed care plan or FFS when the termination of a provider from their MLTSS network would result in a disruption in their residence or employment. We propose to codify this additional cause for disenrollment as § 438.56(d)(2)(iv) and to redesignate the existing text at that paragraph to (d)(2)(v). In paragraph (d)(3), we propose to add text to clarify that disenrollment requests that the MCO, PIHP, PAHP, PCCM, or PCCM entity does not approve would have to be referred to the state for review. This would not change the meaning but we believe it would improve the readability of the sentence. The existing text is otherwise retained in paragraph (d)(5), except to add PCCM entities to its scope as discussed elsewhere.

In paragraph (e)(1), we propose changes for clarification. Currently in paragraph (e)(1) of this section, the timeframe for a state to process a disenrollment request is intended to apply to enrollee requests for disenrollment. The timeframe applies regardless of whether the enrollee submits the request—directly to the state or to the MCO, PIHP, PAHP, PCCM, or PCCM entity (if permitted by its contract with the state.) However, § 438.56(d)(1)(ii) permits states to allow MCOs, PIHPs, PAHPs, and PCCMS to process disenrollment requests. In these instances, the health plan can approve the request, but it cannot actually disapprove the request. Instead, per § 438.56(d)(3), it must forward the request to the state. In these instances, the timeframe for the state to process a disenrollment request referred by the plan is the same as if the enrollee had submitted it directly to the state. To clarify this intent, in paragraph (e)(1), we propose to insert the term ''requests'' after the term ''enrollee'' and replaced the term ''files'' with ''refers.'' No changes are proposed in paragraphs (f) and (g).

c. Beneficiary Support System (§ 438.71)

In existing regulations at § 438.10, we acknowledged the importance of information and disclosure in helping the beneficiary choose a managed care plan. However, we recognize that some beneficiaries may need additional assistance when evaluating their choices. This additional assistance includes having access to personalized assistance—whether by phone, internet, or in person—to help beneficiaries understand the materials provided, answer questions about options available, and facilitate enrollment with a particular health plan or provider. Some states have found that having such personalized assistance has helped to limit the number of beneficiaries assigned through their default enrollment process.

This personalized assistance concept is similar to existing programs in the Marketplace or State Health Insurance Programs (SHIPs) for Medicare beneficiaries, with someone assisting the beneficiary in a helpful, neutral and non-coercive way to make an informed choice that best suits their health care needs. Choice counseling is currently defined in § 438.810 and we propose to move the definition to § 438.2 and define the term as the provision of information and services designed to assist beneficiaries in making enrollment decisions; it includes answering questions and identifying factors to consider when choosing among managed care health plans and primary care providers. Choice counseling does not include making recommendations for or against enrollment into a specific MCO, PIHP, or PAHP.

We propose a new § 438.71, entitled Beneficiary Support System. Proposed paragraph (a) establishes the standard that a state develops and implements a beneficiary support system to provide

support before and after managed care enrollment. Paragraph (b) proposes four minimum functions for a beneficiary support system: Paragraph (b)(1)(i) would ensure that the provision of choice counseling is made available to all beneficiaries, paragraph (b)(1)(ii) would add training on the type and availability of community based resources and supports, paragraph (b)(1)(iii) would require assistance to all beneficiaries in understanding managed care, and paragraph (b)(1)(iv) would add assistance for enrollees who receive or desire to receive LTSS. In paragraph (b)(2), we propose that the system be available to the beneficiaries in multiple ways including phone, internet, in-person, and via auxiliary aids and services when requested. As we discussed in the Collection of Information (COI) section of this proposed rule, we support the use of traditional and electronic means of communicating with beneficiaries.

We propose to add a standard at § 438.71(c)(1) for states to provide choice counseling services for any potential enrollee (that is, prior to first enrollment in managed care) or to managed care enrollees when they have the opportunity to change enrollment or must change enrollment as described in § 438.56(b) and (c). States have the flexibility to decide who can provide choice counseling. However, in paragraph (c)(2), we clarify that any individual or entity providing choice counseling services is considered an enrollment broker under our regulations, and therefore, must meet the independence and conflict of interest standards of § 438.810 to provide those services. This means the entity cannot have a financial relationship with any MCO, PIHP, PAHP, PCCM, or PCCM entity which operates in the state where the entity is providing choice counseling. This would include participating with the MCO, PIHP, PAHP, PCCM, or PCCM entity as a contracted provider. In states where the county is acting as a managed care plan, the county may not provide choice counseling as serving in both capacities is incompatible with the conflict of interest and independence standards. We understand that some entities may receive federal grant funding distinct from Medicaid funding that may require those entities, such as FQHCs or Ryan White providers, to conduct activities similar to those that would fall under the definition of choice counseling. (This is not an exhaustive list of federal grantees and is provided for illustrative purposes). If those entities do not have a memorandum of agreement or contract with the state to provide choice counseling on the state's behalf, such entities would not be required to adhere to the conflict of interest standards in 438.810 under our proposal at § 438.71(c)(2). We request comment on whether entities that provide non-Medicaid federally-financed protections to beneficiaries that includes representation at hearings should be allowed to also contract with the Medicaid agency to provide choice counseling as long as appropriate firewalls are in place; we do propose in paragraph (e)(3)(i) a similar exemption and firewall requirement for such grantees to represent enrollees receiving LTSS from the managed care entity. We would expect such requirements to include appropriate firewalls in both staff responsibilities and billing practices for choice counseling services. We also seek comment on what should constitute the minimum firewall standards between the choice counseling and other federally funded advocacy functions to preserve the independence of the choice counseling.

In proposed paragraph (d), the beneficiary support system would provide training to MCO, PIHP, and PAHP staff and network providers on community based resources and supports that can be linked with covered benefits. Community services often facilitate or promote compliance with service or treatment plans and thus, the managed care plan, provider and beneficiary all benefit from the state ensuring that information on available resources is known and understood by all parties providing or coordinating care for beneficiaries.

We understand that states may include many of these services already within their Medicaid program and we do not intend that states develop a new system of delivering all the functions proposed in § 438.71(e) for MLTSS. Under our proposal, states would be permitted to draw upon and expand, if necessary, those existing resources to meet the standards of this section.

In paragraph (e), we propose four elements for a beneficiary support system specific to beneficiaries who use, or desire to use, LTSS: (1) An access point for complaints and concerns about enrollment, access to covered services, and other related matters; (2) education on enrollees' grievance and appeal rights, the state fair hearing process, and rights and responsibilities; (3) assistance, upon request, in navigating the grievance and appeal process and appealing adverse benefit determinations made by a plan to a state fair hearing; and (4) review and oversight of LTSS program data to assist the state Medicaid Agency on identification and resolution of systemic issues. Proposed paragraph (e)(1) applies to enrollees of MCOs, PIHPs, PAHPs, PCCMS, and PCCM entities while (e)(2) through (e)(4) apply only to MCOs, PIHPs, and PAHPs since they reference the grievance and appeal process which PCCMs are not required to have.

Given the increased complexity of care and service needs for beneficiaries receiving, or in need of, LTSS, we believe this added level of support is appropriate. The proposed changes to this paragraph are discussed in more detail in section I.B.6.e. of this proposed rule. Finally, we note that the proposed scope of services for LTSS beneficiary supports may include what has been traditionally considered ''ombudsman'' services; however, rules concerning Medicaid-reimbursable expenditures remain in place, so we caution that not all ombudsman activities traditionally found in a Long-Term Care Ombudsman office may be eligible for Medicaid payment under this proposal. We issued an informational bulletin on June 18, 2013, entitled ''Medicaid Administrative Funding Available for Long-Term Care Ombudsman Expenditures,'' that provided guidance on this issue. The informational bulletin is available at *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-06-18-2013.pdf*. We request comments on our overall approach to § 438.71.

d. Coverage and Authorization of Services and Continuation of Benefits While the MCO, PIHP, or PAHP Appeal and the State Fair Hearing Are Pending (§ 438.210 and § 438.420)

We group together our discussion of proposals for §§ 438.210 and 438.420 because they address related benefit issues about the receipt and provision of covered services. Section 438.210 establishes standards for authorization periods set by managed care plans and § 438.420 addresses the duration of continued benefits pending appeal resolution. Although the current regulation at § 438.210 addresses MCOs, PIHPs, and PAHPs, the current regulation at § 438.420 addresses only MCOs and PIHPs. We propose to add PAHPs to the subpart F appeal and grievance regulations as discussed in the Appeals and Grievance section of this proposed rule (I.B.1.b.).

Under existing regulations, continuation of benefits during an appeal is tied to coverage and authorization decisions made by the MCO, PIHP, or PAHP. As more managed

care programs include enrollees with ongoing and chronic care needs, including LTSS, we believe it is important that authorization periods for such services reflect the ongoing need for these services to avoid disruptions in care.

While we recognize that MCOs, PIHPs, and PAHPs have flexibility in applying utilization management controls for covered services, exercising that flexibility could result in the inappropriate curtailment of necessary services, particularly for those requiring on-going and chronic care services, including LTSS. We acknowledge that our current standards reflect an acute care model of health care delivery and do not speak to the appropriate medical management of individuals with ongoing or chronic conditions, or the authorization of non-clinical services that maximize opportunities for individuals to have access to the benefits of community living and the opportunity to receive services in the most integrated setting. Therefore, we propose to modernize the language in § 438.210 governing the coverage and authorization of services and establish standards for states through the managed care contract to ensure that MCOs, PIHPs, and PAHPs employ utilization management strategies that adequately support individuals with ongoing or chronic conditions or who require long-term services and supports.

As background, the foundation of coverage and authorization of services is that services in Medicaid must be sufficient in amount, duration, or scope to reasonably be expected to achieve the purpose for which the services are furnished, and services must not be arbitrarily denied or reduced because of the diagnosis or condition of the enrollee. Our proposal would permit a MCO, PIHP, or PAHP to place appropriate limits on a service on the basis of criteria applied under the state plan, such as medical necessity, or for the purpose of utilization control, provided that the services furnished can reasonably achieve their purpose. This is the same standard applied to a state's coverage decisions under the state plan, *see* § 440.230 and we propose to reflect this by revising pertinent text in § 438.210(a).

We propose no changes to § 438.210(a)(1) and (2). In paragraph (a)(3)(i), we propose to delete ''be expected to'' as it is used relative to services reasonably achieving their results and align with the FFS standard in 42 CFR 440.230.

We propose that existing paragraph (a)(3)(iii) be redesignated as (a)(4) and existing paragraphs (a)(3)(iii)(A) and (B) be redesignated without change as paragraphs (a)(4)(i) and (ii), with new paragraphs (a)(4)(ii)(A), (B) and (C). In paragraph (a)(4)(ii)(A), we propose text to incorporate the proposed revisions in paragraph (a)(3)(i) deleting the phrase ''to be expected to'' as it is used relative to services reasonably achieving their purpose in stating a limit on how utilization controls may be used. We also propose to add two new conditions on when and how an MCO, PIHP, or PAHP may impose utilization controls. First, we propose in paragraph (a)(4)(ii)(B) that the state must ensure, through its contracts, that service authorization standards are appropriate for and do not disadvantage those individuals that have ongoing chronic conditions or needing LTSS. The expectation is that clinical services that support individuals with ongoing or chronic conditions, as well as LTSS would be authorized in a manner that reflects the beneficiary's continual need for such services and supports. As this would be a contractual standard for managed care programs that cover both medical and LTSS, we expect states to monitor MCO, PIHP, and PAHP compliance with setting reasonable authorization periods, and have included a standard for monitoring utilization management in our proposed revisions to § 438.66. Second, we propose that utilization controls may not interfere with the enrollee's freedom to choose a method of family planning. Specifically, we propose that utilization controls are permissible so long as family planning services are provided in a manner that protects the enrollee's freedom to choose the method of family planning to be used consistent with § 441.20. We propose this language pursuant with our authority under section 1902(a)(4) of the Act to ensure that beneficiaries, whether receiving family planning services through FFS or managed care, have the same freedom to choose the method of family planning to be used. This proposal does not alter the state's ability under FFS or a managed care plan's ability to apply medical necessity criteria for an individual's request for family planning services but provides that utilization controls that would interfere with an enrollee's freedom to choose the method of family planning would not be permitted. We request comment on this proposal.

We propose that existing paragraph (a)(4) be redesignated as (a)(5) and paragraph (5)(i) is unchanged. In paragraph (a)(5)(ii), we propose to revise the criteria for defining medically necessary services by adding that such criteria must meet the requirements for providing early and periodic screening and diagnosis of beneficiaries under age 21 to ascertain physical and mental defects, and providing treatment to correct or ameliorate defects and chronic conditions found (EPSDT). We believe this addition is necessary to ensure that State definitions of medical necessity comply with federal EPSDT laws. In paragraph (a)(5)(iii)(A), we propose to revise the criteria for defining medically necessary services by adding disease, condition, or disorder that results in health impairment and/or disability. We believe this is more comprehensive and more accurately reflects our intent than the existing provision. In paragraph (a)(5)(iii)(A) through (C), we propose grammatical revisions to accommodate a proposed new paragraph (a)(5)(iii)(D) that would add an LTSS focus by requiring that medically necessary services address the opportunity for an enrollee to have access to the benefits of community living.

In paragraph (b), we propose to add specificity related to LTSS services. No changes are proposed for (b)(1) and (2)(i); however, in (b)(2)(ii) we propose to add ''for medical services'' to address requests for non-LTSS, and in paragraph (b)(2)(iii) we propose to add a standard that MCOs, PIHPs, and PAHPs authorize LTSS based on an enrollee's current needs assessment and consistent with the person-centered service plan. Paragraph (b)(3) proposes to change from referencing treating a condition or disease to addressing medical, behavioral health, or LTSS needs.

The proposed changes in paragraph (c) are to add ''PAHP'' to the standards of this paragraph and revise notices of adverse action to notices of adverse benefit determination. As discussed in section I.B.1.b. of this proposed rule, we propose to add PAHPs to subpart F and replace ''action'' with ''adverse benefit determination.'' Thus, both of these are necessary conforming changes.

In paragraph (c), we also propose to correct the heading to reflect the change from action to adverse benefit determination as discussed in section I.B.1.b. of this proposed rule. We also propose to remove the provision that references notices to providers of adverse benefit determinations need not be in writing as an exception to § 438.404. Provider notices are not currently addressed in § 438.404, thus this reference is erroneous.

The only change proposed to paragraph (d)(1) is to delete ''health'' to make ''condition'' more comprehensive.

We propose in § 438.210(d)(2)(i) and (ii) to change the timeframe for MCOs, PIHPs, and PAHPs to make expedited

authorization determinations within 72 hours, rather than the current standard of 3 working days, after receipt of the request for the service to align expedited authorization determination timeframes with expedited health plan level appeals in proposed § 438.408(b)(3). We discuss in section I.B.1.b. of this proposed rule how these proposed timelines align with the MA and commercial standards for expedited appeals. We are not proposing any to revisions to § 438.210(e)

In section § 438.420, we propose conforming revisions, consistent with other proposals throughout subpart F: Specifically, to change ''action'' to ''adverse benefit determination,'' to add PAHPs to standards currently applicable only to MCOs and PIHPs, and to specify all time limits expressed in days as calendar days. To address the limit on enrollee's access to benefits pending resolution of an appeal, we also propose to eliminate the link between the duration of continued benefits pending appeal and the original service authorization period. Thus, we propose to delete existing § 438.420(c)(4) that permits MCOs and PIHPs to discontinue coverage of services pending appeal when the time period or service limits of a previously authorized service has been met. The removal of this paragraph would mean that an enrollee must continue to receive benefits without interruption, if elected by the enrollee, through the conclusion of the SFH process if the enrollee appeals an MCO's, PIHP's, or PAHP's adverse benefit determination. This change would apply to all authorized services covered by the MCO, PIHP, or PAHP as § 438.420. We believe this a critical enrollee protection given the nature and frequency of many ongoing services, particularly for enrollees receiving LTSS.

In addition, in § 438.420(d), we propose that the MCO's, PIHP's, or PAHP's ability for recoupment from the beneficiary under a final adverse decision be addressed in the contract and that such practices be consistent across both FFS and managed care delivery systems within the state. Under both managed care and FFS, the right to continuation of benefits is not exercised without potential financial risk to the beneficiary of payment for services provided if the final decision is adverse to the beneficiary. The decision to hold the beneficiary financially liable for such services is left to the state under § 431.230(b) and that decision would be applied equally to FFS and managed care programs. For example, if the state does not exercise the authority for recoupment under § 431.230(b) for FFS, the same practice must be followed by the state's contracted MCOs, PIHPs, and PAHPs. We request comments on the proposed revisions to §§ 438.210 and 438.420.

e. Continued Services to Beneficiaries and Coordination and Continuity of Care (§ 438.62, § 438.208)

To ensure consistent continuity of care and coordination of services for beneficiaries, we are proposing revisions to § 438.62 and § 438.208.

The existing regulatory framework for coordination of care focuses on three elements: (1) All enrollees must have an ongoing source of primary care; (2) a person or entity will coordinate the care provided by the MCO, PIHP, or PAHP; and (3) additional assessments and treatment plans are in place for individuals identified by the state as having special health care needs. In 2002, when the current regulations were finalized, the use of managed care for delivery of LTSS or providing medical services to more complex populations was not prevalent and, therefore, not substantially reflected in the regulations.

The proposed changes discussed below aim to align the Medicaid managed care framework with other public and private programs and improve coordination and continuity of care. To that end, we propose the following: Set standards for transition plans when a beneficiary moves into a new MCO, PIHP, or PAHP; expand beyond the emphasis on primary care when considering care coordination; strengthen the role of the assigned care coordinator; ensure there is more accurate and timely data gathering and sharing; and include enrollees with LTSS needs in the identification, assessment and service planning processes. These proposed changes would modify sections § 438.62 and § 438.208.

(1) Transition Between Medicaid Delivery Systems (§ 438.62)

Our only explicit transition of care standards included in current Medicaid managed care regulations (codified at § 438.52) focus on when a beneficiary is mandated into a single MCO, PIHP or PAHP in a rural area. We believe there should be transition of care standards for all Medicaid beneficiaries transitioning from one delivery system to another within Medicaid (even MCO to MCO), and not just rural area enrollees.

We propose no changes to paragraph (a) other than to add PCCM entity as discussed elsewhere in this rule. We propose to add a standard to § 438.62(b) which would require that states have a transition of care policy in place for individuals moving to managed care from FFS, or from one MCO, PIHP, PAHP, PCCM, or PCCM entity to another when an enrollee without continued services would experience serious detriment to their health or put them at risk of hospitalization or institutionalization. Under this proposal, states would define the transition policy, as long as it meets the standards proposed in paragraph (b)(1), and would have the flexibility to determine the types of enrollees for which the MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities would need to provide transition activities. Paragraph (b)(1) proposes that transition policies include: Permitting the enrollee to continue to receive the services they are currently receiving from their current provider for a specified period of time in paragraph (b)(1)(i); referring the enrollee to an appropriate participating provider in (b)(1)(ii); assuring that the state or MCO, PIHP or PAHP comply with requests for historical utilization data in (b)(1)(iii); and assuring that the enrollee's new provider is able to obtain appropriate medical records in (b)(1)(iv). We note here that references to ''services'' mean services covered under the contract, which would include prescription drugs if the managed care plan is obligated to provide such services under the contract. We also propose, at paragraph (b)(1)(v), that additional procedures for the transition plan may be specified by the Secretary as necessary to ensure continued access to services for an enrollee to prevent serious detriment to the enrollee's health or to reduce the risk of hospitalization or institutionalization. We request comment on these proposed elements and whether we should propose any other provisions.

In paragraph (b)(2), we propose that states include a transition of care policy standard in their MCO, PIHP, and PAHP contracts. We propose to provide flexibility for states to decide whether to apply the state developed policy consistently to their MCOs, PIHPs, and PAHPs, or whether to permit the health plans to have different policies, as long as the state's minimum standards are met. We believe this approach achieves an appropriate balance between assuring ongoing care for individuals who have significant needs while permitting states flexibility to determine how best to implement these transitions. At a minimum, the transition policies should be included in the state's comprehensive quality strategy and

included in information provided to potential enrollees.

(2) Ongoing Source of Primary Care (§ 438.208(a))

In the existing Medicaid managed care regulations, there is a singular focus on establishing primary care relationships between providers and enrollees. However, this focus does not sufficiently address an enrollee's need for ongoing sources of all types of care, including ongoing relationships with behavioral health or LTSS providers. In consideration of our proposal to ensure continued access to care appropriate to an individual's needs, we also believe changes to the exceptions for MCOs, PIHPs, and PAHPs serving dually eligible individuals are necessary. We propose no changes to paragraph (a)(1). We propose to delete paragraph (a)(2)(i) as it is redundant to proposed language in paragraph (b)(1); however, doing this necessitates incorporating the existing provisions in paragraph (a)(2)(ii) into (a)(2). We propose minor technical corrections in § 438.208(a)(3)(i) to replace the outdated reference to ''Medicare+Choice plan'' with ''Medicare Advantage organization.'' Additionally, in § 438.208(a)(3)(ii), we propose that the decision to grant an exception to a MCO serving dually eligible individuals would be based on the needs of the population served rather than on what services are covered under the contract.

(3) Care Coordination Activities (§ 438.208(b))

The Agency for Healthcare Research and Quality (AHRQ) defines care coordination as ''deliberately organizing patient care activities and sharing information among all of the participants concerned with a patient's care to achieve safer and more effective care. This means that the patient's needs and preferences are known ahead of time and communicated at the right time to the right people, and that this information is used to provide safe, appropriate, and effective care to the patient.'' [12] These concepts are embedded in the regulations governing the MA program as well as the Marketplaces. Both the MA program and the Marketplace regulations seek to ensure that the needs of enrollees are assessed, and that care is coordinated across settings and with services delivered inside and outside the health plans. Although we believe most MCOs, PIHPs, and PAHPs are already doing these activities, we propose to update our regulations to align with the governing policies of the MA program and the Marketplaces. At the same time, we propose several modifications to § 438.208(b) and (b)(1): (1) To revise the language in paragraph (b)(1) from services ''furnished to'' enrollees, to services ''accessed by'' enrollees, to more adequately describe the entire range of services covered by the regulations; (2) to remove references to ''primary'' to ensure each enrollee receives access to an ongoing source of care appropriate to their needs, regardless of whether the service provider is considered a primary care provider; and (3) to remove the words ''health care'' to explicitly recognize that MCOs, PIHPs, and PAHPs may coordinate not only health care services but a full range of community based support services to provide services in the most integrated setting to enrollees.

We propose to expand the standards in paragraph (b)(2) so that care coordination activities at MCOs, PIHPs, and PAHPs involve coordination between care settings in paragraph (b)(2)(i) and coordination with services provided outside of the MCO, PIHP or PAHP, including with another MCO, PIHP, or PAHP in paragraph (b)(2)(ii) and FFS Medicaid in paragraph (b)(2)(iii). We request comment on including an additional standard relating to community or social support services in paragraph. These could include linking enrollees to services through organizations such as Protection and Advocacy organizations, Legal Aid, Aging and Disability Resources Centers, Centers for Independent Living, Area Agencies on Aging, or United Way 311 lines. Given the historically high rate of utilization of these services by the Medicaid population, Medicaid managed care plans have experience in facilitating and coordination access to these services. This language would acknowledge existing industry practice. We request comment on this approach and on any potential costs associated with this addition.

We believe that health plans must ensure that appropriate information is available to, shared with, and maintained by all providers and the MCO, PIHP, or PAHP that is coordinating the care. Therefore, we propose to add standards in new paragraphs (b)(3) and (b)(5) that each MCO, PIHP and PAHP make their best effort to complete an initial health risk assessment within 90 days of the effective date of enrollment for all new enrollees and that all providers, practitioners and suppliers maintain and share an enrollee health record according to MCO, PIHP, or PAHP standards under our authority at section 1902(a)(4) of the Act. We also propose to remove phrase ''with special health care needs'' from existing paragraph (b)(3) (redesignated at (b)(4)) and change the word ''its'' to ''any'' in that same paragraph to broaden the standard for sharing assessment results to avoid duplication of services. The standard of an initial health assessment is explicit in the MA regulations in § 422.112(b)(4)(i), so we believe these changes establish consistent standards for MCOs participating in Medicare and Medicaid, thereby easing administrative burden. Finally, in the redesignated paragraph (b)(4) regarding the sharing of the results of an enrollee's need assessment with another MCO, PIHP, or PAHP that serves the enrollee, we propose to add the state as a recipient of that information if the state (through FFS) provides coverage of some services to an enrollee, such as behavioral health or pharmacy coverage. In addition, we propose that existing paragraph (b)(4) be moved without change to paragraph (b)(6).

(4) Long-Term Services and Supports (§ 438.208(c))

The current Medicaid managed care regulations were written at a time when a managed care delivery system was not frequently utilized for LTSS. With states using managed care to deliver covered services to populations with more complex needs, care coordination that is appropriate for individuals using LTSS becomes an important component of managed care. We propose to codify the elements contained in our May 2013 guidance for managed long-term services and supports [13] programs operated under section 1915(b) waivers and section 1115(a) demonstration projects. See section I.B.6.e. of this proposed rule for more information on the 2013 guidance.

We propose changes in paragraph (c)(1) of § 438.208 to add enrollees who need LTSS to the populations for which the state must have mechanisms to identify these enrollees to the MCO, PIHP, or PAHP. We propose a change to paragraph (c)(1)(i) to reflect that the mechanisms required in paragraph (c)(1) must be included in the state's comprehensive quality strategy as defined in proposed § 438.340. We also propose that states may use their staff, their enrollment brokers, and the MCOs, PIHPs, and PAHPs as part of these

[12] AHRQ Web site: *http://www.ahrq.gov/professionals/prevention-chronic-care/improve/coordination/index.html.*

[13] *http://www.medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/downloads/1115-and-1915b-mltss-guidance.pdf.*

identification mechanisms. There are no changes proposed to paragraph (c)(1)(ii). Other changes we are proposing to paragraph (c) include:

- Amending paragraph (c)(2) so that assessments for both individuals in need of LTSS as well as those with special health care needs are comprehensive and are conducted by appropriate LTSS service coordinators having qualifications specified by the state or the MCO, PIHP, or PAHP, or by health care professionals. We believe this to be a critical standard to avoid insufficient service or treatment plans or a disruption in services to enrollees.
- Amending paragraph (c)(3) to propose clarifications that treatment plans would also be considered service plans and that they are developed for individuals needing LTSS in addition to individuals with special health care needs.
- Amending paragraph (c)(3)(i) to propose that treatment or service plans are developed by the enrollee's provider or an individual meeting the health plan or state's service coordination provider standards in consultation with other health care professionals caring for the enrollee. This change is intended to permit a MCO, PIHP, or PAHP to use internal staff for service coordination, even though those staff would not be considered providers and, thus, not permitted to perform assessments under current regulation.
- Adding new standards under paragraphs (c)(3)(ii) to propose that treatment or service plans developed for those in need of LTSS conform with the person centered planning standards found in § 441.301(c)(1) and (2). This proposal is consistent with the HCBS final rule released in 2014.
- Redesignating current paragraphs (c)(3)(ii) and (iii) without change as paragraphs (c)(3)(iii) and (iv). Proposing a new standard under paragraph (c)(3)(v) that service and treatment plans be reviewed and revised upon reassessment of the enrollee's functional needs, at least every 12 months, when the enrollee's circumstances or needs change significantly, or at the request of the enrollee.

No changes are proposed for paragraph (c)(4).

f. Advancing Health Information Exchange

Health information technology and the electronic exchange of health information is an important tool for achieving the care coordination objectives proposed in section § 438.62, § 438.208, and other parts of this proposed rule. The Department supports the principle that all individuals, their families, their healthcare and social service providers, and payers should have consistent and timely access to health information in a standardized format that can be securely exchanged among the patient, providers, and others involved in the individual's care (HHS August 2013 Statement, ''Principles and Strategies for Accelerating Health Information Exchange.'') Further, the Department is committed to accelerating health information exchange through the use of health information technology (health IT) across the broader care continuum and across payers. Health IT that facilitates the secure, efficient and effective sharing and use of health-related information when and where it is needed is an important contributor to improving health outcomes, improving health care quality and lowering health care costs. Health IT can help health care providers recommend treatments that are better tailored to an individual's preferences, genetics and concurrent treatments. In addition, it can help individuals make better treatment decisions and health-impacting decisions outside of the care delivery system.

In January 2015, the Office of the National Coordinator for Health Information Technology (ONC) published ''Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap'' (available at *http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf*) for public comment. This draft document focuses on how interoperable health IT can enable better health and wellness for all Americans, regardless of where they live, learn, work and play.

In addition, ONC has released a draft of the ''2015 Interoperability Standards Advisory'' (available at *http://www.healthit.gov/standards-advisory*) for public comment; the public comment period is open until May 1, 2015. This draft document contains an initial list of the best available standards and implementation specifications to enable priority health information exchange functions. Providers, payers, and vendors are encouraged to take these ''best available standards'' into account as they implement interoperable health information exchange across the continuum of care, including care settings such as behavioral health, long-term and post-acute care, and community service providers (*e.g.,* home and community-based service providers).

We encourage states, MCOs, PIHPs, PAHPs, PCCMs, PCCM entities, and other stakeholders to utilize health information exchange and certified health IT to effectively and efficiently help providers improve internal care delivery practices, support management of care across the continuum, enable the reporting of electronically specified clinical quality measures (eCQMs), and improve efficiencies and reduce unnecessary costs. We welcome comment on how we might reinforce standards through future rulemaking or guidance to states and plans as standards become more mature and adoption of certified health IT increases. For example, as standards become available to electronically integrate long-term services and supports, we could reference them in guidance documents that could then inform contractual requirements for vendors.

g. Managed Long-Term Services and Supports (§ 438.2, § 438.3, § 438.70, § 438.71, § 438.214, § 438.816)

MLTSS refers to an arrangement between state Medicaid programs and MCOs, PIHPs or PAHPs through which the MCO, PIHP, or PAHP receives a capitated payment for providing long-term services and supports (LTSS). MLTSS programs have grown significantly over the past decade and are expected to increase even more in the coming years. Recognizing this significant shift in delivery system design, we developed ten key principles inherent in a strong MLTSS program. These principles were released on May 21, 2013, in guidance [14] for states using a section 1915(b) waiver or section 1115(a) demonstration to implement a MLTSS program. We propose to revise the Medicaid managed care regulations to ensure that all MLTSS programs, regardless of underlying authority, operate in accordance with these elements. The elements are incorporated in proposed changes throughout this part and include LTSS specific changes in sections discussed below. Some of the changes we propose—while prompted by MLTSS considerations—apply broadly to all beneficiaries, and so have been applied to all managed care programs.

(1) Defining Long-Term Services and Supports

We propose to add a definition of LTSS to § 438.2 for purposes of applying the rules in part 438 of this chapter; however, the definition would not be applicable to any other part of title 42 of the CFR. Our proposal defines LTSS as ''services and supports provided to beneficiaries of all ages who have

[14] *http://www.medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/downloads/1115-and-1915b-mltss-guidance.pdf.*

functional limitations and/or chronic illnesses that have the primary purpose of supporting the ability of the beneficiary to live or work in the setting of their choice, which may include the individual's home, a provider-owned or controlled residential setting, a nursing facility, or other institutional setting.'' We intend for community based services within the scope of this definition to be largely non-medical in nature and focused on functionally supporting people living in the community. Examples of what we would consider community based LTSS include Home- and Community-Based Services (HCBS) delivered through a section 1915(c) waiver, section 1915(i), or section 1915(k) state plan amendments, as well as personal care services otherwise authorized under the state plan. We note that individuals with chronic illness that may receive LTSS include individuals with mental health conditions and substance use disorders.

We considered defining LTSS in a way that references specific services in title 42 of the CFR such as HCBS and Nursing Facility services (defined in part 440), but determined that would be too limiting and not allow for future innovation in what services are considered LTSS. We request comment on the proposed definition and whether it is appropriate in scope.

2. Codifying MLTSS Guidance

The principles in CMS' May 2013 guidance were developed after extensive review of numerous published findings, interviews with states as to lessons learned in the start-up and implementation of MLTSS programs, and recommendations from our HHS partners and other external stakeholders. The 10 elements identified in our 2013 guidance and proposed for regulation are:

1. Adequate Planning
2. Stakeholder Engagement
3. Enhanced Provision of Home and Community Based Services
4. Alignment of Payment Structures and Goals
5. Support for Beneficiaries
6. Person-centered Processes
7. Comprehensive, Integrated Service Package
8. Qualified Providers
9. Participant Protections
10. Quality

In the following discussion, we describe how we have incorporated these elements into this proposed rule. As noted previously, the elements are incorporated in proposed changes throughout this part, and we reference those sections of this proposed rule where the associated proposals are further discussed. In this section, we summarize the LTSS specific proposals in the context of the ten elements of our guidance and explain how, together, they strengthen MLTSS programs. We request comment on the incorporation of these proposals.

Element 1: Adequate Planning: We believe the most effective MLTSS systems are the result of a thoughtful and deliberative planning process with a clear vision for the program. Thoughtful planning in the development of MLTSS programs helps to ensure a smooth transition for persons with LTSS needs as they transition from FFS to managed care delivery systems. We propose to incorporate this element in the existing regulatory structure as follows:

- Amending § 438.66 to propose that there is appropriate state monitoring and accountability of the program that includes readiness reviews. While this standard would apply broadly to all managed care programs and is discussed in section I.B.6.c. of this proposed rule, LTSS, as a covered service under the contract, would be included in this review to the same extent as all other covered services.
- Amending § 438.10 to propose additional standards for enrollee and potential enrollee materials, including information on transition of care, who to contact for support and other standards for provider directories. The specific proposed changes to § 438.10 are discussed in the Member materials preamble of this proposed rule in section I.B.6.d. While LTSS is not specifically referenced, states (under § 438.10(e)) and managed care plans (under § 438.10(g) and (h)) to provide information on all covered benefits and provider directory information.

Element 2: Stakeholder Engagement: Successful MLTSS programs have developed a structure for engaging stakeholders regularly in the ongoing monitoring and oversight of the MLTSS program. Educated stakeholders, including beneficiaries, providers, and advocacy groups inform decisions as to what works and what does not in the managed care system, allowing the state to design systems that are responsive to the needs of stakeholders and to address any implementation issues discovered early in the process. While Medicaid already has a standard for a Medical Care Advisory Committee (MCAC) outlined in § 431.12 and while in some states this forum has proved to be a useful venue for actionable feedback regarding a state's managed care program, the MCAC in other states may not provide the opportunity to receive meaningful input from MLTSS stakeholders. Our proposed provisions for gathering stakeholder input are discussed in more detail in section I.B.6.h. of this proposed rule.

Element 3: Provision of Home and Community Based Services: All MLTSS programs must be implemented consistent with the Americans with Disabilities Act (ADA) and the Supreme Court's *Olmstead* v. *L.C., 527 U.S. 581 (1999)* decision. Further, all contracts with MCOs, PIHPs, and PAHPs must comply with all applicable federal and state laws including the ADA under our current regulations. Proposed § 438.3(o) is discussed in section I.B.2.a. of this proposed rule.

Element 4: Alignment of Payment Structures and Goals: Payment to MCOs, PIHPs, and PAHPs should support the goals of MLTSS programs to improve the health of populations, support the beneficiary's experience of care, support community integration of enrollees, and reduce costs. We incorporated this element to propose that states include MLTSS program elements in the annual program summary report proposed under § 438.66. These program elements are discussed in section I.B.6.c. of this proposed rule.

Element 5: Support for Beneficiaries: Support and education, including enrollment and disenrollment assistance and advocacy support services, are critical for all beneficiaries in a MLTSS program. As discussed in more detail in section I.B.5.c of this proposed rule, we are incorporating this element by proposing § 438.71, which would have states provide a beneficiary support system, including choice counseling services. While applicable to all managed care programs, the proposed changes to § 438.71 would provide assistance to those with complex needs, such as those receiving LTSS, who would benefit most from these activities. We also note that under proposed § 438.71(d) the state would provide training to MCOs, PIHPs, PAHPs, PCCMs, PCCM entities, and network providers on the specific community-based resources and supports that can be linked with covered benefits. Finally, in § 438.71, as described previously, states would incorporate four beneficiary support functions for all individuals using, or expressing a desire to use, LTSS within a managed care program:

- Provide an access point for complaints and concerns pertaining to the MCO, PIHP, PAHP, PCCM, or PCCM entity on the enrollment process, access to services, and other related matters (§ 438.71(e)(1));

• Educate beneficiaries on the grievance and appeal process, the SFH process, enrollee rights and responsibilities, as well as resources outside of the MCO, PIHP or PAHP (§ 438.71(e)(2));

• Assist in navigating the grievance and appeal process for MCOs, PIHPs and PAHPs or SFH excluding providing representation (§ 438.71(e)(3)); and

• Review and oversight of LTSS program data to assist the state Medicaid Agency on identification, remediation, and resolution of systemic issues (§ 438.71(e)(4)) .

We also incorporate this element by proposing a new for cause reason for disenrollment for enrollees receiving LTSS in § 438.56(d)(2)(iv), which is discussed in section I.B.5.b. of this proposed rule. This proposal recognizes that provider network changes can have a significant impact on those enrolled in MLTSS programs, since some providers are integral to residential and employment services and supports. Therefore, if the state does not permit participants enrolled in MLTSS to switch managed care plans (or disenroll to FFS), at any time, states should permit MLTSS enrollees to disenroll and switch to another MCO, PIHP, PAHP, or FFS when the termination of a provider from their MLTSS network would result in a disruption in the enrollee's use of that provider. Under this proposal, an enrollee would be permitted to change their MCO, PIHP, or PAHP if their residential, institutional, or employment supports provider terminates their participation with the enrollee's current MCO, PIHP, or PAHP.

Finally, we are incorporating this element in our proposed new section § 438.816 *Expenditures for Independent Consumer Support Services for Enrollees using LTSS* that would describe the conditions that must be met for the state to claim FFP for the LTSS-specific beneficiary support system activities proposed in § 438.71(e). We have modeled this standard, in part, on current rules for administrative services claiming and, in part, on the current rules for enrollment broker services. We propose, consistent with our current policy, that beneficiary support services for MLTSS enrollees are eligible for administrative match subject to certain standards. Specifically, in paragraph (a), we propose that costs must be supported by an allocation methodology that appears in the state's Public Assistance Cost Allocation Plan; in paragraph (b) that the costs do not duplicate payment for activities that are already being offered or should be provided by other entities or paid by other programs; in paragraph (c) that the person or entity providing the service must meet independence and conflict of interest provisions applicable to enrollment brokers in § 438.810(b) standard; and in paragraph (d) that the initial contract or agreement for services in this section be reviewed and approved by CMS. More specific guidance around claiming for Ombudsman services can be found in the CMCS Informational Bulletin released on June 18, 2013, available at *http://medicaid.gov/Federal-Policy-Guidance/Downloads/CIB-06-18-2013.pdf*.

Element 6: Person Centered Process: Ensuring that beneficiaries' medical and non-medical needs are met and that they have the quality of life and level of independence they desire within a MLTSS program starts with person-centered processes including comprehensive needs assessments and service planning policies. We are incorporating this element through proposed changes to § 438.208(c) requiring identification, assessment, and treatment/service planning for individuals receiving LTSS who are enrolled in a MCO, PIHP or PAHP. This proposal is discussed in section I.B.4.e. of this proposed rule and would have an overall effect of shifting from a strictly medical, acute care focus to one that addresses all covered services.

Element 7: Comprehensive, Integrated Service Package: In instances in which a state managed care program divides services between contracts or delivery systems, it is important that there is robust coordination and referral by the managed care plan to ensure that the beneficiary's service plan, which may include LTSS, is comprehensive and person-centered. We incorporate this element by proposing to expand § 438.208(b)(2), so that MCOs, PIHPs, and PAHPs coordinate an enrollee's care between settings of care, with services received from another MCO, PIHP, or PAHP, and with services received from FFS. This proposal is discussed more fully in section I.B.5.e. of this proposed rule.

Element 8: Qualified Providers: As with traditional managed care programs, MCOs, PIHPs, and PAHPs in a MLTSS program must have an adequate network of qualified providers to meet the needs of their enrollees. While current credentialing and network adequacy systems have been developed based on an acute and primary care service delivery model, managed care networks also meet the needs of MLTSS beneficiaries, including adequate capacity and expertise to provide access to services that support community integration, such as employment supports, and the provision of training and technical assistance to providers. We propose the following changes to incorporate this element:

• Amending § 438.68(b)(2) to propose that states establish time and distance standards specifically for MLTSS programs. This proposal addresses time and distance standards for LTSS provider types in which the enrollee must travel to the provider and the use of standards other than time and distance for LTSS provider types that travel to the enrollee to deliver the service. We believe it is important to recognize that standards must reflect the high utilization of services outside of the traditional medical office setting by enrollees using LTSS. Other changes to § 438.68 are discussed in section I.B.6.a. of this proposed rule.

• Amending § 438.206(c)(3) to propose that MCOs, PIHP, and PAHPs ensure that network providers have capabilities to ensure physical access, accommodations, and accessible equipment for enrollees with physical and mental disabilities. Given the high number of enrollees with a disability receiving some LTSS, we believe this to be an important factor when evaluating qualified providers in a MLTSS program. Other changes to § 438.206 are discussed in section I.B.6.a. of this proposed rule.

• Amending § 438.207(b)(1) to propose that MCOs, PIHPs, or PAHPs submit documentation to the state to demonstrate that it complies with offering the full range of preventive, primary care, specialty care, and LTSS services adequate for the anticipated number of enrollees. Under this proposal, the state would review the submitted documentation and certify its adequacy in paragraph (d) of this section. These changes are discussed in section I.B.6.a. of this proposed rule.

• Amending § 438.214(b)(1) to propose that each state establish a credentialing and re-credentialing policy that addresses all the providers, including LTSS providers, covered in their managed care program regardless of the type of service provided by such providers. We propose this to emphasize the importance of a credentialing and re-credentialing policy for all provider types for the services covered under the contracts. We also propose that each MCO, PIHP, and PAHP must follow the state policy but do not propose to prohibit additional policies at the state or managed care plan level.

Elements 9 and 10: Participant Protections and Quality: Participant health and welfare is an important tenet in a program providing LTSS. We are

incorporating these two elements by proposing to add a contract standard in § 438.330(b)(6) that MCOs, PIHPs, and PAHPs participate in state efforts to prevent, detect, and remediate all critical incidents. We intend this standard to be interpreted to apply to incidents that adversely impact enrollee health and welfare and the achievement of quality outcomes described in the person centered plan. Under this proposal, states would specify the MCO, PIHP, or PAHP's roles and responsibilities related to these activities in the MCOs, PIHPs, and PAHP's contract.

We believe that a quality system for MLTSS is fundamentally the same as a quality system for a state's entire managed care program, but should include MLTSS-specific quality elements. Other revisions previously discussed in this section address the delivery of MLTSS services in a high-quality manner, and we specifically propose to amend § 438.330(b)(5) to include references to specific MLTSS quality considerations. Under proposed paragraph (b)(5), the MCO, PIHP, or PAHP would have mechanisms to assess the quality and appropriateness of care provided to LTSS enrollees including between settings of care and as compared to the enrollee's service plan. In addition, under § 438.330(e)(1)(iii), we propose that the state includes the results of any rebalancing efforts by the MCO, PIHP, or PAHP for individuals using LTSS in its annual program review. These provisions are discussed in more detail in section I.B.6.b. of this proposed rule.

These ten elements are the basis for many of our proposals related to LTSS provided through a managed care delivery system. We solicit comment on the extent to which our proposals—those discussed specifically above and the other LTSS-specific provisions in this proposed rule—incorporate the elements.

h. Stakeholder Engagement in LTSS

Since stakeholder engagement plays a critical role in the success of a MLTSS program, we propose that states and managed care plans must have appropriate minimum mechanisms in place to accomplish this. Therefore, we propose to add a new § 438.70 regarding the state's creation and maintenance of a stakeholder group so that opinions of beneficiaries, providers, and other stakeholders are solicited and addressed during the design, implementation, and oversight of the MLTSS program. We propose significant flexibility for states in meeting this standard, specifically that states set the composition of the stakeholder group and the frequency of meetings to ensure meaningful stakeholder engagement. Our proposal specifically uses a ''sufficiency'' standard rather than setting quantitative parameters for the composition of the group or the frequency of meetings. We request comments on the overall approach for these changes, as well as on the composition of the stakeholder group, stakeholder group responsibilities, and approach to meeting frequency for both states and managed care plans.

In concert with the new § 438.70, we also propose a new § 438.110. While the stakeholder group proposed in § 438.70 is maintained by the state, each MCO, PIHP, and PAHP should establish a regular process to solicit direct input on the enrollees' experiences. Therefore, in paragraph (a), we propose that for any MCO, PIHP, or PAHP contract that includes LTSS, the MCO, PIHP, or PAHP must establish and maintain a member advisory committee. Paragraph (b) proposes that the committee include a reasonably representative sample of the covered LTSS populations. We included PAHPs in this standard, because we understand there are some PAHPs in operation that cover LTSS.

6. Modernize Regulatory Standards

a. Availability of Services, Assurances of Adequate Capacity and Services, and Network Adequacy Standards (§ 438.206, § 438.207, § 438.68, § 440.262)

Assessment of the network adequacy of contracted MCOs, PIHPs, and PAHPs is a primary component of our determination of a state's readiness to implement and sustain managed care programs. Under section 1932(b)(5) and (c)(1)(A)(i) of the Act, respectively, an MCO must provide assurances about its capacity and ability to provide services and a state must develop a quality assessment and improvement strategy for its managed care program that includes access standards for enrollees. Relying on this authority and on section 1902(a)(4) of the Act, we established in the 2002 Medicaid managed care final rule standards for the availability of services and assurances of adequate capacity from MCOs, PIHPs, and PAHPs. Since that time, our ongoing work with states has revealed variation in how states define adequate health plan networks and the frequency with which states evaluate MCO, PIHP, and PAHP network adequacy. The OIG conducted a study of network adequacy standards used by states and confirmed our findings regarding a high level of variation in evaluation method and frequency: *http://oig.hhs.gov/oei/reports/oei-02-11-00320.pdf*. We propose a new regulation section and revisions to existing regulations to establish minimum standards in this area. The proposed changes aim to maintain state flexibility while modernizing the current regulatory framework to reflect the maturity and prevalence of Medicaid managed care delivery systems, promote processes for ensuring access to care, and align, where feasible, with other private and public health care coverage programs. To that end, we propose to set standards to ensure ongoing state assessment and certification of MCO, PIHP, and PAHP networks, set threshold standards for the establishment of network adequacy measures for a specified set of providers, establish criteria for developing network adequacy standards for MLTSS programs, and ensure the transparency of network adequacy standards. These proposed changes would create a new § 438.68 specific to the development of network adequacy standards for medical services and LTSS and modify § 438.206 and § 438.207.

(1) Requirements for the Network Adequacy Standards Set by the State for a Specified Set of Providers (§ 438.68)

As discussed above, our current regulatory framework provides states with significant flexibility to determine whether an MCO, PIHP, or PAHP adequately makes services accessible and available to enrollees under the managed care contract. In addition, our regulations were developed at a time when managed care for the delivery of LTSS was extremely limited and involved only a handful of programs limited in geographic scope. We propose to establish standards for states to follow in the development of Medicaid managed care network adequacy standards that address medical services, behavioral health services, and LTSS. In accordance with our underlying goal to align Medicaid managed care standards with other public programs where appropriate, we analyzed the network adequacy standards applicable under the Marketplace and the MA program to inform our proposed rule. As background, we provide a short summary of the standards utilized by these programs below.

A health plan offered by an issuer must be certified as a Qualified Health Plan (QHP) to offer coverage in the Marketplace. To meet QHP certification standards, health plans must maintain a network that: (1) Includes essential community providers; (2) is sufficient in number and types of providers,

including providers that specialize in mental health and substance use disorder services, to assure that all services would be accessible without unreasonable delay; and (3) is consistent with the network adequacy provisions of section 2702(c) of the PHS Act. *See* 45 CFR 156.230(a). The Marketplace standard of requiring a health plan to ensure a sufficient number and types of providers is included in a network to ensure accessibility of services is similar to Medicaid managed care standards. To ensure this standard is met, the Federally Facilitated Marketplace (FFM) receives attestations from organizations applying for certification of their health plans as QHPs. During 2014, the FFM utilized a combination of issuer accreditation status, the identification of states with review processes at least as stringent as the QHP certification standard, and network access plans as part of its evaluation of health plans' network adequacy. In the Final 2015 Letter to Issuers, the FFM discussed its policies about network adequacy and accessibility of services in connection with QHP certification. (*http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2015-final-issuer-letter-3-14-2014.pdf, pp.17–18*). For 2015 and 2016 certification, the FFM has moved to assessing provider networks using a ''reasonable access'' standard to identify networks that fail to provide access without unreasonable delay, focusing on those areas which have historically raised network adequacy concerns, including hospital systems, mental health providers, oncology providers, and primary care providers.

CMS has a detailed approach for setting standards in the MA program that includes the minimum number of providers, maximum travel time, and maximum travel distance per county for all provider types covered under the MA organization contract. To determine the minimum number of providers per county, we calculate the 95th percentile of beneficiaries to cover based on annual MA enrollment and the designation of a county as large metro, metro, micro, rural or Counties with Extreme Access Criteria (CEAC). To establish minimum provider ratios for all provider types in MA organizations, CMS relies on primary and secondary research on utilization patterns and clinical needs of the covered population to calculate the number of providers per 1,000 beneficiaries per county. We also set time and distance criteria by interfacing mapped beneficiary residence locations against provider practice locations. Health plans applying for MA participation must ensure that at least 90 percent of the beneficiaries residing in a county have access to at least one provider or facility of each type within the published time and distance criteria and must complete a comprehensive worksheet demonstrating compliance with these standards per desired counties. If an applicant's network does not meet the criteria, we would issue a deficiency notice, which would trigger the applicant's ability to request an exception to the minimum number of providers and/or maximum time/distance criteria for a particular provider type. A template outlines specific supporting documentation that the applicant must show that local community patterns of care support the proposed provider network for which the applicant is requesting an exception. For a further guidance on the network adequacy criteria for MA organizations, *see http://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/Downloads/CY2014-HSD-Provider-and-Facility-Specialties-Criteria-Guidancev2.pdf*.

In the existing rules for Medicaid managed care and the rules finalized for Marketplaces and QHPs, the network adequacy standards are similar in that we did not establish detailed and specific time and distance standards or provider to enrollee ratios but deferred to each Marketplace or state to develop specific standards; our regulatory framework in both cases relies heavily on attestations and certifications from the applicable health plan, with supporting documentation, about the adequacy of the network. Consistent with the primary role of states in this, we intend to keep that general approach for the Medicaid program, rather than taking the more detailed approach used in the MA program. This approach is also consistent with our role in the Medicaid managed care context compared to MA; while we have an oversight and administrative role in both cases, the state has the primary responsibility for administering and monitoring the Medicaid managed care program. We propose to add a new § 438.68 that would stipulate that the state must establish, at a minimum, network adequacy standards for specified provider types.

Proposed paragraph (a) specifies that a state that contracts with an MCO, PIHP, or PAHP must develop network adequacy standards that satisfy the minimum parameters in § 438.68. This proposed provision is the counterpart to our proposal at § 438.206 that the state ensures that enrollees of MCOs, PIHPs, and PAHPs have access to all services covered under the state plan in a manner that is consistent with the state-set standards for access and availability. These proposed regulations would apply to contracts that cover medical services, behavioral health services, and LTSS; the standards for LTSS proposed in (b)(2) and (c)(2) are described in the MLTSS-specific discussion at the end of this section.

Proposed paragraph (b)(1) would stipulate that states must establish time and distance standards for the following network provider types: Primary care (adult and pediatric); OB/GYN; behavioral health; specialist (adult and pediatric); hospital; pharmacy; pediatric dental; and additional provider types when it promotes the objectives of the Medicaid program for the provider type to be subject to such time and distance standards. We intend this proposal to be applicable only to the services covered under the MCO, PIHP, or PAHP contract. We propose that states, at a minimum, establish time and distance standards as such standards are currently common in the commercial market and many state Medicaid managed care programs; further, we believe time and distance standards present a more accurate measure of the enrollee's ability to have timely access to covered services than provider-to-enrollee ratios. We request comment on whether we should propose a different national type of measure for states to further define, such as provider-to-enrollee ratios, or whether we should permit states the flexibility to select and define the type of measure for the network's adequacy of the specified provider types. Additionally, we request comment on whether we should define the actual measures to be used by states such that we would set the time and distance or provider-to-enrollee ratio standard per provider type, per county, or other appropriate geographic basis.

Given the large number of pediatric Medicaid enrollees, we believe it is important for states and plans to specifically include pediatric primary, specialty, and dental providers in their network adequacy standards. Network adequacy is often assessed without regard to practice age limitations which can mask critical shortages and increase the need for out-of-network authorizations and coordination. We request comment on whether standards for behavioral health providers should distinguish between adult and pediatric providers. We considered adding family planning providers to the list of providers that would be subject to time and distance standards but declined to do so because section 1902(a)(23) of the Act guarantees freedom of choice of

family planning providers and providers of family planning services would include physicians and OB/GYNs. We request comment on this approach.

Appreciating that provider networks can vary between geographic areas of a state and states have different geographic areas covered under managed care contracts, as proposed in paragraph (b)(3), states would have to establish time and distance standards for specified provider types that reflect the geographic scope of the program. Our proposal would permit states to vary those standards in different geographic areas to account for the number of providers practicing in a particular area. Our proposal would not limit states to only the mandatory time and distance standards but also would have states consider additional elements when developing network adequacy standards.

Proposed paragraph (c)(1) specifies the minimum factors a state must consider in developing network adequacy standards; most of the elements proposed here are currently part of § 438.206(b)(1) as considerations for MCOs, PIHPs, and PAHPs in developing their managed care networks. These are: Anticipated Medicaid enrollment; expected utilization of services; taking into account the characteristics and health needs of the covered population; number and types of health care professionals needed to provide covered services; number of network providers that are not accepting new Medicaid patients; and the geographic location and accessibility of the providers and enrollees.

Disparities in access to care related to demographic factors such as race, ethnicity, language, or disability status are, in part, a function of the availability of the accessible providers who are willing to provide care and are competent in meeting the needs of populations in medically underserved communities. Additionally, new enrollees in Medicaid managed care, including those who are dually eligible for Medicare and Medicaid, may present with multiple chronic conditions and need the services of multiple specialists. Absent an adjustment for new populations enrolled in a state's Medicaid managed care program, existing plan networks may be inadequate to meet new enrollees' needs.

Accordingly, we propose changes to the factors that we are proposing to move from current § 438.206(b)(1). We propose to make existing § 438.206(b)(1)(ii) into separate factors that the state must consider: Expected utilization and the characteristics and health needs of the covered population; these would be codified as § 438.68(c)(1)(ii) and (iii) and use substantially the same language as in the current regulation. Similarly, we propose two separate factors, to be codified at § 438.68(c)(1)(vi) and (viii), in place of the current § 438.206(b)(1)(v), which are geographic location and accessibility. Although we propose to use the same language regarding geographic considerations, we propose in § 438.68(c)(1)(viii) that each state must also consider the ability of providers to ensure physical access, accommodations, and accessible equipment available for Medicaid enrollees with physical or mental disabilities, with proposed additional standards that the accommodations be reasonable and that the ability of providers to ensure culturally competent communication be considered as well. Also, we propose to add a new element, at proposed paragraph (c)(1)(vii), so that states must also consider the ability of network providers to communicate with limited English proficient enrollees in their preferred language when the state is developing time and distance access standards.

In effect, our proposal is that the states develop standards by which to review the provider networks used in Medicaid managed care, which should ensure that these elements are also taken into consideration by MCOs, PIHPs, and PAHPs that maintain and monitor the provider networks. We intend that compliance with our proposal would be best met if states look to standards established by the insurance regulator (for example, Department of Insurance, or similar agency within the state) for commercial insurance, and the standards set under the MA program, as well as historical patterns of Medicaid utilization—including utilization specific to sub-populations that may be more relevant to the Medicaid program than in commercial or Medicare markets—to inform the standards the state establishes for Medicaid managed care programs under § 438.68. The time and distance standards per county are published annually in the MA Health Services Delivery (HSD) Reference file, which is accessible at the MA Applications page at *http://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/index.html?redirect=/MedicareAdvantageApps/*. While we are not proposing to dictate the particular time and distance standards or set a quantitative minimum to be adopted by a state, we intend to assess the reasonableness of the particular standard adopted by a state under our proposed § 438.68 within the context of other existing standards should the need for such evaluation arise.

We recognize that situations may arise where a MCO, PIHP, or PAHP may need an exception to the state established provider network standards. A number of states currently permit exceptions, and have a process for seeking exceptions, under the state standards imposed on a managed care entity under existing §§ 438.206 and 438.207. Therefore, proposed § 438.68(d) provides that, to the extent a state permits an exception to any of the provider network standards, the standard by which an exception would be evaluated must be specified in the contract and must be based, at a minimum, on the number of health care professionals in that specialty practicing in the service area. Under our proposal, the state must monitor enrollee access to providers in managed care networks that operate under an exception and report its findings to us as part of its annual managed care program monitoring report provided under proposed § 438.66. We invite comment on our proposal related to exceptions a state may grant to its network adequacy standards established by the state for Medicaid MCOs, PIHPs, or PAHPs.

Finally, in proposed paragraph (e), to promote transparency and public input for these managed care network adequacy standards, states would have to publish the network adequacy standards developed in accordance with § 438.68 on the Medicaid managed care Web site under § 438.10. In addition, states would have to make these standards available at no cost, upon request, to individuals with disabilities through alternate formats and using auxiliary aids and services.

(2) Criteria for Developing Network Adequacy Standards for MLTSS Programs (§ 438.68(b)(2) and (c)(2))

Unlike medical and behavioral health services, there are no commonly used access standards for LTSS in the commercial market or in Medicare, as LTSS are primarily covered through Medicaid. As states have begun to deliver LTSS through managed care, they have created standards for their individual programs, which vary widely. Likewise, the level of oversight by the state that is necessary to enforce network adequacy standards for LTSS provided through managed care contracts varies, ranging from a minimal level of effort to an in-depth review of

service plan authorizations compared to actual claims experience. We expect that, as MLTSS programs mature, states and managed care plans would develop innovative ways to ensure access to a high quality network of LTSS providers. As those initiatives evolve, we propose here minimum standards for how states adopt network adequacy standards to ensure the availability of critical services and supports for beneficiaries as more of them transition to MLTSS programs.

LTSS is commonly thought of as being provided in a beneficiary's home, like personal care services, but LTSS can also be delivered in a provider's office, in various community locations, such as places of employment or recreation, and in an institution. Therefore, considerations for setting network adequacy standards should include time and distance, and other standards for ensuring access to adequate services. In § 438.68(b)(2), we propose that states set standards that encompass time and distance and other measures of access when delivering LTSS through their managed care plans; the type of standard that the state would have to adopt under our proposal depends on whether the enrollee or the provider must travel to provide the services. While we do not specify a specific set of providers in our LTSS-specific proposal, we expect the state to consider all LTSS delivered through managed care when developing the standards which may include, but are not limited to, institutional, community-based, residential, and employment supports providers, depending on the program. Proposed paragraph (c)(2) sets forth the elements that states would have to consider when developing standards for LTSS in a managed care program. Under our proposal, when developing time and distance standards, states would consider the same elements as when setting medical services network standards and also consider strategies to ensure the health and welfare of enrollees using LTSS and to support community integration of individuals receiving LTSS. LTSS enrollees may have different needs than those enrollees only using acute, primary, and behavioral health services. For example, assessing network adequacy for individuals receiving LTSS in their place of residence may be based on enrollee-to-provider ratios. Additionally, the ability of the enrollee to choose a provider is a key protection that must be considered when developing network standards for MLTSS so we propose to include that here. Supporting health and welfare and choice of provider are important tenets already in place in the LTSS FFS system and MLTSS should maintain those protections. Finally, our proposal includes a substantive standard which we would apply to determine if states must include other considerations under § 438.68(c)(2)(iv).

(3) Availability of Services (§ 438.206 and § 440.262)

Currently, in § 438.206, states have to ensure that all services covered under the state plan are available and accessible to enrollees of MCOs, PIHPs, and PAHPs. Throughout § 438.206, we propose to use the terms ''network provider'' and ''health care professional'' as applicable to be consistent with the proposed new definitions of these terms (see section I.B.8. of this proposed rule) and to provide greater clarity to our regulations. We consider such proposed changes largely technical in nature.

We propose to revise paragraph (a), which currently sets forth the basic rule for the availability of services, to add a new sentence such that states must ensure that MCO, PIHP, and PAHP provider networks for services covered under the MCO, PIHP, or PAHP contract meet the state's network adequacy standards established under proposed § 438.68. In this paragraph, we also propose to clarify that services are to be made available and accessible in a timely manner. The timeliness standard is currently in paragraph (b)(4), pertaining to access to out-of-network providers, and in paragraph (c)(1); therefore we believe it is appropriate to incorporate timeliness into the general rule for availability of services in paragraph (a).

In paragraph (b), we propose substantive changes only to (b)(1) and (b)(5). We propose to move the second sentence of (b)(1) and the provisions at existing paragraphs (b)(1)(i) through (b)(1)(v) to the new § 438.68(c) so that all regulatory standards related to the measurement of adequate MCO, PIHP, and PAHP provider networks are contained in one section. We propose to add text to (b)(1) to clarify that the sufficiency and adequacy of the provider network and access to services is for all enrollees, including those with limited English proficiency and physical or mental disabilities. We propose to amend paragraph (b)(5) to include PAHPs in the payment standard for covered services that are provided out-of-network. We consider this a technical correction as the preamble for the 2002 final rule refers to PAHPs (67 FR 41038) and we believe PAHPs were inadvertently excluded from the final regulatory text.

Currently, in paragraph (c)(1), MCOs, PIHPs, or PAHPs have to follow state-defined timely access standards for services covered under the contract, and such standards must be enumerated in the MCO, PIHP, or PAHP contract. We do not propose any substantive changes to existing paragraph (c)(1) but are proposing changes to improve the readability and clarity of the regulation text. We also clarify our intent to interpret and apply the provisions here as requiring states to set standards for timely access to all state plan services covered under the managed care contract. For purposes of setting timely access standards, state plan services may be reasonably classified as routine, urgent, or emergency care. We believe that for access standards to be effective, states will need to have mechanisms in place for ensuring that those standards are being met by the managed care plan networks. We considered requiring a mix of approaches, such as conducting enrollee surveys, reviewing encounter data, calculating and reporting of HEDIS measures related to access, implementing secret shopper efforts, and a systematic evaluation of consumer service calls. We request comment on approaches to measuring enrollee's timely access to covered services and to evaluating whether managed care plan networks are compliant with such standards. We also request comment on the value of requiring some or all of these mechansims for ensuring that access standards are being met.

In paragraph (c)(2), we propose to add to the standards to ensure that MCOs, PIHPs, and PAHPs participate in states' efforts to promote access in a culturally competent manner to all enrollees. This includes those with limited English proficiency, diverse cultural and ethnic background, disabilities, and regardless of an enrollee's gender, sexual orientation, or gender identity. We are also proposing to add a corresponding standard in a new § 440.262 so that the state would similarly ensure nondiscrimination in access to services under FFS. We believe that the obligation for the state plan to promote access and delivery of services without discrimination is necessary to assure that care and services are provided in a manner consistent with the best interest of beneficiaries under section 1902(a)(19) of the Act. The best interest of beneficiaries is appropriately met when access is provided in a non-discriminatory manner; adopting these additional methods of administration is also necessary for the proper operation

of the state plan under section 1902(a)(4) of the Act.

We propose to add a new paragraph (c)(3) to emphasize the importance of network providers having the capabilities to ensure physical access, accommodations, and accessible equipment for the furnishing of services to Medicaid enrollees with physical or mental disabilities. This is mirrored in proposed § 438.68(c)(1)(vii) relating to considerations for developing network adequacy standards.

(4) Assurances of Adequate Capacity and Services (§ 438.207)

Currently in § 438.207(a), states have to ensure, through the contracts and submission of assurances and documentation from managed care entities, that the managed care health plans have the capacity to serve the expected enrollment in accordance with state-set standards for access to care; under current § 438.207(b), the specified documentation must demonstrate the adequacy of the range of covered services and the provider network. We propose to keep the existing regulation text in paragraphs (a) and (b) substantially the same, with a minor amendment to specify in paragraph (b)(1) that supporting documentation must also address LTSS. This change is consistent with the broader proposal to incorporate LTSS throughout part 438, where applicable. Although we do not specifically reference LTSS anywhere else in our proposals for § 438.206 or § 438.207, the standards outlined in those sections are applicable to all managed care programs, including MLTSS.

Under current § 438.207, states, through their contracts, must stipulate that MCOs, PIHPs, and PAHPs to submit documentation that their network is sufficient in number, mix, and geographic distribution to meet, in accordance with state-set standards, the needs of anticipated enrollees. Under paragraph (c), such documentation must be submitted at least at the time MCOs, PIHPs and PAHPs enter into a contract with the state or at any time there has been a significant change in operations that would affect the adequacy of the network. The state has a corresponding responsibility, under paragraph (d), to review the documentation and certify to CMS that the applicable MCO, PIHP, or PAHP meets the state's standards for availability of services.

Appreciating that health plan networks are not static, we have considered the periodicity at which network adequacy documentation should be submitted by plans to be reviewed and certified by states. We propose to amend § 438.207 so that health plans have to submit documentation and the state to certify the adequacy of the provider networks on at least an annual basis. We request comment on the appropriate timeframe for submission and review of network certification materials.

To implement this proposal, we propose to amend paragraph (c)(2) to add annual submission of the documentation and to redesignate the regulation text currently at § 438.207(c)(2) as (c)(3), which, stipulates submission of documentation of adequate networks when there has been a significant change in the health plan's operations that would affect capacity and services; we consider such changes as warranting a reexamination of provider networks outside of an annual cycle. As in the existing regulation, changes such as enrollment of a new population or changes in benefits, service area, or payment would trigger a submission of documentation. We propose that a significant change in the composition of a MCO, PIHP, or PAHP's network itself would also trigger a submission of documentation to be codified in § 438.207(c)(3)(i). For example, a significant change in the composition of the provider network would occur when the only participating hospital terminates the provider contract, or similarly when a hospital that provides tertiary or trauma care exits a health plan network. We also propose minor edits to introductory text in paragraph (c)(3) to improve the readability of the paragraph.

In paragraph (d) of § 438.207, addressing the obligation of the state to review documentation from the MCO, PIHP, or PAHP and submit an assurance to us that the managed care plan meets the state's standards for access to services, we propose to add an explicit standard that the submission include documentation of the analysis supporting the certification of the network for each contracted MCO, PIHP, or PAHP. We believe that this is appropriate because it would demonstrate to us how the state evaluates plan compliance with state standards and that the state's assurance is supported by the data. In addition, we are proposing to replace the word ''certify'' with ''submit an assurance of compliance'' to more clearly describe the responsibility of the state under paragraph (d). Finally, we are not proposing any revision to § 438.207(e), which establishes our right to inspect the documentation provided under § 438.207. We request comments on the overall approach to § 438.207.

b. Quality of Care (Subparts D and E of Part 438)

Section 1932(c) of the Act established quality assurance standards for Medicaid managed care programs, specifically, a quality assessment and improvement strategy and an external independent review of contracting MCOs. Regulations at 42 CFR part 438, subparts D (Quality Assessment and Performance Improvement) and E (External Quality Review) implemented this statute; subpart D became effective on August 13, 2002 (67 FR 40989) and subpart E became effective on March 25, 2003 (68 FR 3586). Based on our authority under section 1902(a)(4) of the Act, we expanded the scope of the regulations to capitated entities in addition to MCOs. The existing regulations describe quality standards for all states contracting with MCOs, PIHPs, and in some cases PAHPs, for the delivery of Medicaid services to beneficiaries. This proposed rule would modify these standards.

Approaches to assessing quality, access, and timeliness of care have evolved significantly over the past 10 years. At the federal level, CHIPRA, the American Recovery and Reinvestment Act (ARRA), the Affordable Care Act, the National Quality Strategy, and the CMS Quality Strategy all build on one another to decrease burdens, improve alignment, and encourage innovative approaches to quality measurement and improvement. In developing this proposed rule, we recognized how states have expanded the use of managed care for the delivery of primary care, acute care, behavioral health services, and LTSS to Medicaid beneficiaries. Throughout the rule, we propose changes to maximize the opportunity to improve health outcomes over the lifetime of individuals. Specifically, we propose to strengthen quality measurement and improvement efforts in managed care by focusing on the following three principles:

1. *Transparency:* Public reporting of information on quality of care is a widely recognized tool for driving improvements in care. A key component in designing health care quality transparency initiatives is the use of meaningful and reliable data that is comparable across health plans, providers, and programs. The regulatory changes proposed here are intended to improve transparency with the goal of increasing both state and health plan accountability in the quality of care provided to Medicaid beneficiaries. This would help stakeholders (including consumers) to engage in informed advocacy, compare the performance of

providers and health plans, and make informed program and plan choices.

2. *Alignment with other systems of care:* Aligning, where appropriate, quality standards for Medicaid managed care with that of MA and the Marketplace would result in a simplified and integrated approach to quality measurement and improvement. The regulatory changes proposed here would incorporate the theme of alignment by improving oversight and strengthening programmatic operations to result in more comprehensive, coordinated care across states, and a reduction of administrative burden where possible.

3. *Consumer and Stakeholder Engagement:* Consumer and stakeholder engagement is particularly important when designing an approach to measuring quality for Medicaid managed care, including programs delivering LTSS. Providing consumers with information about their health plan is one tool for engaging them in health care decision-making; however, another useful tool is consumer participation in the development of state strategies for improving care and quality of life. The regulatory changes proposed here would strengthen the role of the consumer in health care decision-making through new tools to enhance active engagement.

(1) Proposed Revisions of Subpart D

(a) Subpart D Title and Sub-Headings

As discussed in the proposed revisions to subpart E below, sections related to the quality strategy found in subpart D would be moved to subpart E. We propose to make minor conforming changes to subpart D and to change the name from ''Quality Assessment and Performance Improvement'' to ''MCO, PIHP, and PAHP Standards.'' We believe this change would more accurately describe the remaining sections of subpart D, which address MCO, PIHP, and PAHP activities, some of which are measured as part of the state quality strategy. Additionally, we propose to remove the subheadings found in subpart D to be consistent with the remaining subparts in part 438. These subheadings would no longer be necessary because the section titles discuss what types of standards are found in subpart D.

(b) Removal of § 438.200, § 438.202, § 438.218, and § 438.226

As mentioned in section I.B.6.b(1)(a), the proposed consolidation of all quality-related standards under subpart E would render § 438.200, which describes the quality-centric scope of subpart D, unnecessary. We propose to remove § 438.200 in its entirety.

We propose to remove § 438.202, due to the standards we propose in the new part 431, subpart I.

We propose to remove § 438.218, which incorporates enrollee information standards in § 438.10 into the state's quality strategy. Proposed changes to both enrollee information standards at § 438.10 and the elements of a state's comprehensive quality strategy at § 438.340 would render § 438.218 duplicative and unnecessary.

Similarly, we propose to remove § 438.226, which incorporates the enrollment and disenrollment standards in § 438.56 into the state's comprehensive quality strategy. Because we propose deleting these elements from inclusion in a state's comprehensive quality strategy (see § 438.340), it would render § 438.226 unnecessary.

(2) Proposed Revisions of Subpart E

(a) Scope (§ 438.310)

This section currently explains the basis, scope, and applicability of subpart E, which provides details on the external quality review (EQR) process for MCOs and PIHPs. Generally, subpart E covers the selection of EQR reviewers, their qualifications, types of EQR-related activities, the availability of EQR results, and the circumstances in which a Medicare or private accreditation review may be used to satisfy elements of the EQR. Because we propose to move and revise the existing standards related to both the managed care quality strategy and the quality assessment and performance improvement program from subpart D to subpart E, we propose in paragraph (a) to include section 1932(c)(1) of the Act as part of the statutory basis for the quality strategy provisions. In addition, we propose to include section 1902(a)(19) of the Act as part of the statutory basis, which maintains that each state ''provide such safeguards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients.'' We believe this authority would be applicable to both existing provisions of the regulation and some of our proposed changes.

Under the existing quality provisions, states contracting with MCOs and PIHPs must draft and implement a quality strategy and all MCOs and PIHPs must undergo an annual EQR. As states expand their use of managed care for other services or populations, it is increasingly important to develop a comprehensive approach to measuring and improving quality. Because some PAHPs might provide dental or behavioral health services, we propose that states address such plans in the state's comprehensive quality strategy, with performance results publicly available in the EQR technical reports. Therefore, we propose to rely on the authority of section 1902(a)(4) of the Act to apply the quality standards of section 1932(c) of the Act to PAHPs and PIHPs. Throughout subpart E, as well as in § 438.10, we propose the addition of ''PAHPs'' as necessary to reflect this proposal. Currently, some PAHPs function as brokers of non-emergency medical transportation (NEMT), so much of subparts D and E would not apply to these NEMT PAHPs. The provisions that apply to NEMT PAHPs are discussed in the proposed changes to § 438.9.

We also propose to delete the specific reference to health insuring organizations (HIOs), throughout this subpart E because with the exception of those HIOs that are expressly exempt by statutory law, HIOs under our proposal would be treated in the same manner as a MCO. We propose in § 438.310(b) to identify the scope of subpart E, including specifications for a process ensuring review and approval of managed care plans, quality ratings, the quality strategy, and external quality reviews. In paragraph (c)(1), we propose that these specifications apply to MCO, PIHPs, and PAHPs (including certain HIOs as mentioned in this proposed rule). Finally, we propose in § 438.310(c)(2) to address the elements related to quality assessment and improvement for states contracting with PCCM entities. Specifically, we propose that states assess the performance of PCCM entities consistent with § 438.3(r); such assessment would include a review of at least the mechanisms to detect under- and over-utilization of services, performance measures, and program review (by reference to specific provisions proposed at § 438.330).

(b) Definitions (§ 438.320)

This section currently defines terms related to the EQR process, including EQR, EQRO, financial relationship, quality, and validation. We do not propose to change the definitions for EQR, financial relationship, and validation, other than the addition of ''PAHP'' as necessary. Because the EQR process involves an analysis and evaluation of the quality, timeliness, and access to services that a health plan furnishes, we propose adding a

definition for access and to update the definition of quality. We also propose to clarify the definition of ''external quality review organization.''

The current regulations do not include a definition for access; however, there are availability of services standards in § 438.206 and proposed network adequacy standards in § 438.68. We propose a new definition for access, as it pertains to EQR, by referring to the timely provision of services in accordance with the network adequacy standards proposed in § 438.68 and availability of services standards in § 438.206.

The current regulations define ''external quality review organization'' (EQRO) in terms of its qualifications and the services it performs, namely the competence and independence standards in § 438.354, and the EQR and other EQR-related activities set forth in § 438.358. We propose revising this definition to clarify that an entity must also hold an active contract with a state to perform EQR or EQR-related activities to be considered an EQRO. Therefore, an entity itself would not be considered an EQRO if it has not yet entered into an EQRO arrangement with a state even if it meets all qualifications for entering into such a contract. We believe that this is implicit in our current regulations and propose this primarily as a clarification.

The current regulations define quality, as it pertains to EQR, as ''the degree to which a MCO or PIHP increases the likelihood of desired health outcomes of its enrollees through its structural and operational characteristics and through the provision of health services that are consistent with current professional knowledge.'' We propose to modify this definition to reflect that this professional knowledge be evidence-based and supported by current science. We believe that modifying the definition in this way would recognize the current efforts that states and their plans engage in to stay up-to-date on the latest scientific findings and translate those findings into effective clinical practices. We also propose to modify this definition by tying performance measure trends and performance improvement outcomes to the definition of quality (which, for individuals receiving MLTSS, would include considerations around quality of life). We believe this would highlight the importance of the relationship between these efforts and overall plan quality and is supported by our proposed use of standardized performance measurement tools.

(c) Quality Assessment and Performance Improvement Program (§ 438.330, Formerly § 438.240)

The current § 438.240 describes standards related to a quality assessment and performance improvement program. In our proposed § 438.330(a)(1), we would carry over this standard, and again, propose incorporating PAHPs for the reasons mentioned elsewhere in this preamble. Since the finalization of the managed care rules in 2002, the scope of managed care in states has greatly expanded. We propose including the word ''comprehensive'' to signal that states should consider all populations and services covered by managed care when developing quality assessment and performance improvement standards for their contracted managed care health plans.

In § 438.330(a)(2), we propose to revise the existing regulatory language at § 438.240(a)(2) to permit us, in consultation with states and other stakeholders, to specify standardized performance measures and topics for performance improvement projects (PIPs) for inclusion alongside state-specified measures and topics in state contracts with their MCOs, PIHPs, and PAHPs. We propose to add that we would also establish a methodology for quality ratings, which is discussed in more detail below in connection with our proposed § 438.334. Our proposed addition of ''through a public notice and comment process'' would clarify the manner in which CMS would proceed with this set of performance measures and/or PIP topics. We propose this would be accomplished after notice and public comment to ensure that states, beneficiaries, and other stakeholders have the opportunity to provide input during the measure selection process. However, our proposal would also continue to support flexibility for states to adopt state-specific performance measures and performance improvement topics for their managed care plans.

We propose, in § 438.330(a)(2)(ii), to adopt a mechanism for an exemption from the nationally identified PIP topics and metrics for states that request one. Reasons for an exemption might be if a selected measure is not applicable to the population enrolled in a state's managed care program (for example, a measure related to behavioral health services, but the state carves those services out of managed care); if the number of enrollees for a particular measure is too small to calculate the measure; or if a MCO's, PIHP's, or PAHP's performance on a particular measure has exceeded the 90th percentile for more than 3 years in a row. We are considering whether these or other criteria are appropriate for the exemption process and invite comment on other instances in which a state may believe an exemption would be necessary.

In paragraph (b), we propose to recodify and slightly reorganize the substance of existing § 438.240(b) consistent with our proposal to move all quality program provisions to subpart E. In paragraph (b)(1), for purposes of reorganization and consolidation of standards related to PIPs, we propose moving the description of what PIPs are designed to achieve to paragraph (d). This would result in having all PIP-specific details in one place. In paragraph (b)(2), we propose to modify the existing language from ''submit performance measurement data'' to ''collect and submit performance measurement data.'' We believe this change would clarify that the collection of relevant data is necessary as part of the submission process.

We recognize that MCOs, PIHPs, and PAHPs delivering LTSS should evaluate and measure the quality and appropriateness of services in a manner that is designed for LTSS and the population receiving those services (for example, inclusion of quality of life measures when selecting performance measures). Because of this, we propose in paragraph (b)(5) that MCOs, PIHPs, and PAHPs have specialized mechanisms to assess the quality and appropriateness of care furnished to enrollees receiving LTSS. This would include an assessment of the care that individuals receive when moving to different service settings, such as residential to community (or vice versa) or residential to hospital (or vice versa). We encourage states to consider including language in their MCO, PIHP, and PAHP contracts that incorporates the use of surveys to assess the experience of beneficiaries receiving LTSS as a key component of the plan's LTSS assessment process. We solicit comment on the current use of such surveys and how they may best be used to improve the delivery of LTSS to beneficiaries and to improve their experience of care. We also propose that MCOs, PIHPs, and PAHPs compare the services that an individual receiving LTSS has obtained with those that were in the individual's LTSS treatment plan. Lastly, we propose in paragraph (b)(6) that MCOs, PIHP, and PAHPs participate in efforts by the state to prevent, detect, and remediate critical incidents, based on applicable standards on the state for home and community based waiver programs.

In paragraph (c)(1), we propose to delete the reference to § 438.204(c), as we propose removing this from the managed care elements for inclusion in a state's comprehensive quality strategy, as described in the proposed § 438.340 (currently § 438.204); our other proposed revisions to paragraphs (c)(1) through (c)(3) are to conform it to the remainder of our proposal and to incorporate PAHPs.

We propose the addition of paragraph (c)(4), which would focus on performance measurement as it relates to LTSS. Under this proposal, MCOs, PIHPs, and PAHPs that provide LTSS would include, in addition to other performance measures under paragraphs (c)(1) through (c)(3), LTSS-specific performance measures that examine, at a minimum, beneficiaries' quality of life and a plan's rebalancing and community integration outcomes. We expect these measures would support and align with a plan's quality assessment and performance improvement program function as proposed in paragraph (b)(5). States whose MLTSS programs include a self-direction option should consider including measures specific to self-direction under this paragraph.

As mentioned above, we propose moving the description of what a PIP is designed to achieve to paragraph (d)(1) for purposes of better organization and readability. To streamline quality improvement standards for plans exclusively serving dual eligible beneficiaries, we propose the option in paragraph (d)(3) for states to substitute an MA plan's quality improvement project conducted under § 422.152(d) in the place of a Medicaid PIP. This would prevent unnecessary duplication and increase flexibility for plans exclusively serving dual eligibles.

Finally, under our proposal in § 438.330(e), states would continue to annually review the impact and effectiveness of each MCO's, PIHP's, and PAHP's quality assessment and improvement program. We also propose in paragraph (e)(1)(iii), that the state incorporate the results of any LTSS balancing efforts (community integration) at the managed care plan level into this program review. This would expand the program review from a single focus on acute care services, making it more comprehensive and valuable. We request comment on our approach to § 438.330.

(d) State Review and Approval of MCOs, PIHPs, and PAHPs (New § 438.332)

This new section proposes that as a condition of entering a contracting relationship with a state, MCOs, PIHPs, and PAHPs undergo a review on the basis of performance in accordance with standards that are at least as stringent as the standards used by a private accreditation entity approved or recognized by CMS for purposes of accrediting MA Organizations and QHPs. This process would align standards of review for Medicaid managed care plans with those found in other health care coverage options.

As described elsewhere in this preamble, aligning, where appropriate, Medicaid managed care quality initiatives with those of MA and the Marketplace would result in a streamlined approach to quality measurement and improvement. Under Section 1311 of the Affordable Care Act, QHPs are to be accredited, by a CMS-recognized entity, based on a number of criteria, including clinical quality measures, patient experience, utilization management, quality assurance, complaints and appeals, and network adequacy and access. We have issued regulations at 45 CFR 156.275 to govern the accreditation process for QHPs. In general, MA Organizations do not have to obtain accreditation; however, if an MA Organization elects to become accredited by a CMS-approved accrediting organization it may be ''deemed'' compliant in one or more of six standards set forth in section 1852(e)(4)(B) of the Act. For QHPs and MA Organizations, CMS has the ability to recognize or approve accrediting organizations; to become recognized or approved, the entity must demonstrate to CMS that its standards are at least as stringent as those established by Medicare and the Marketplace. In addition, specialized plans for special needs individuals, per amendments made by section 3205 of the Affordable Care Act, must receive approval from the National Committee for Quality Assurance (NCQA).

By proposing a process similar to accreditation for Medicaid managed care plans, we would align the expectations for these plans in a manner that is consistent with other coverage options. Alignment of Medicaid plan review standards with those in other coverage options would protect beneficiaries by ensuring that plans meet certain performance levels and continue to do so over time. Furthermore, we believe this proposal would assist states in identifying plans that have a commitment to providing high quality care.

While having a set of performance standards for Medicaid managed care plans will benefit the Medicaid program and its beneficiaries, state flexibility is critical given the wide variety of state managed care contracting arrangements. Therefore, we propose to give states a choice of two options (or a combination of those options) to comply with our proposal. Both options are mechanisms to achieve the goal of attracting and retaining higher performing plans for participation in the Medicaid program.

In paragraph (a)(1), we propose the first option for states, which is a state review and approval process that would be at least as stringent as that used by a private accreditation entity. Our proposal also incorporates the standards used in the Marketplace and MA to set the parameters for the review and approval process. Specifically, we propose that the state review and approval be based on standards that are at least as stringent as those used by the accreditation organizations that are recognized by CMS in MA or the Marketplace. We anticipate that states would purchase standards from one of the CMS-recognized accrediting organizations for this purpose. We propose in paragraph (a)(2) that states review and reissue approval of each MCO, PIHP, and PAHP at least once every 3 years. In paragraph (a)(3), we propose that MCOs, PIHPs, and PAHPs maintain performance with state standards at the level necessary for approval for as long as they participate in the state's managed care program.

The second option, proposed in paragraph (b), would allow a state to elect to use evidence that an MCO, PIHP, or PAHP has obtained accreditation by one of the CMS-recognized private accrediting entities to deem compliance with the review and approval standard proposed in paragraph (a)(1). This would allow states to take advantage of existing private sector infrastructure for the accreditation process and deem compliance based on the private independent accreditation of an MCO, PIHP, or PAHP. While there are costs for health plans associated with obtaining accreditation, we believe that this would be a valuable investment for plans, would provide an efficient method of state oversight, and would increase accountability on the part of Medicaid health plans. Additionally, the costs associated with private accreditation may be offset by a reduction in duplicative EQR processes.

In paragraph (b)(2), we propose that if a state were to elect this option, the MCO, PIHP, or PAHP would need to authorize the private accreditation entity to provide the state with copies of its most recent accreditation survey. This would allow the state to ensure that the MCO, PIHP, or PAHP has obtained an acceptable level of

accreditation status (as proposed in § 438.322(b)(2)(i)), review the actual findings of the survey (as proposed in § 438.322(b)(2)(ii)), and determine when the accreditation is due to expire (as proposed in § 438.322(b)(2)(iii)).

The two options proposed in this section are not exclusive; a state may elect to use the first option for one plan and the second option for other plans. In other words, states would be able to establish their own review and approval process, but also allow plans that have obtained private accreditation to submit documentation in accordance with the second option. We believe that this flexibility will enable states to use this process in a manner that fits with a state's vision and resources for managing Medicaid managed care quality and performance.

Finally, in paragraph (c), we propose that states make the final approval status of each MCO, PIHP, and PAHP, publicly available on the state's Medicaid Web site, regardless of whether this is based on the state review or private accreditation option. Examples of information that a state might post include: Whether the approval is based on state review or the accreditation deeming process; if accreditation, which entity has accredited the plan and what level of accreditation the plan obtained; the expiration date of the approval, etc. We solicit comment on this approach to achieving our goals of attracting and retaining higher performing plans for participation in the Medicaid program and ensuring that performance standards are aligned across the health care system. We request comments on our approach to § 438.332.

(e) Medicaid Managed Care Quality Rating System (New § 438.334)

This new section proposes minimum standards that all states contracting with MCOs, PIHPs, and PAHPs would use in developing and implementing a Medicaid managed care quality rating system. The publication of standardized, reliable, and meaningful quality information for each MCO, PIHP, and PAHP would increase transparency regarding Medicaid managed care health plan performance. Such a system would support alignment and consumer and stakeholder engagement, and enable beneficiaries to consider quality when choosing a Medicaid health plan. States would be able to use this information in formulating quality improvement goals and objectives, state contracting and enrollment decisions, and quality oversight of health plans. In addition, the proposed rating system would also assist states in evaluating the prior performance of Medicaid health plans looking to enter new markets.

To develop this proposal, we examined both the quality rating system established for the QHPs offered through the Marketplaces and the five-star rating system used for MA and Prescription Drug Plans. These existing systems were developed through a process that accommodates public comment. Section 1311(c)(3) of the Affordable Care Act directed the Secretary to develop a system that would rate QHPs offered through the Marketplaces and enable consumers to compare such QHPs based on relative quality, price, and enrollee satisfaction. In a November 19, 2013 **Federal Register** notice (78 FR 69418), the Department solicited comment on a process for selecting and organizing measures for the QHP quality rating system (*http://www.gpo.gov/fdsys/pkg/FR-2013-11-19/pdf/2013-27649.pdf*). This notice with comment set forth, among other things, the proposed general principles of the QHP quality rating system as well as proposed measures that were evidence-based and aligned, to the maximum extent possible, with measures in other federal, state, and private sector health care programs.

In the 2015 Quality Rating System and Qualified Health Plan Enrollee Experience Survey Technical Guidance (available online at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Health-Insurance-Marketplace-Quality-Initiatives.html*), we announced the final domains and measures that will be used in 2015 to beta test the QHP quality ratings.[15] The selected domains and measures are grouped under three summary indicators, which align with CMS and national priorities under the National Quality Strategy: (1) Clinical Quality Management; (2) Member Experience; and (3) Plan Efficiency, Affordability and Management. Beneath these three summary indicators fall a set of eight domains that represent important aspects of quality: (1) Clinical Effectiveness; (2) Patient Safety; (3) Care Coordination; (4) Prevention; (5) Access; (6) Doctor and Care; (7) Efficiency and Affordability; and (8) Plan Service. Each domain then has a set of associated performance measures (19 clinical and 10 survey measures), which all factor in to create a rating that consumers may use when evaluating health plan options. The QHP quality rating system uses a five-star scale, similar in style and format to that of the MA and Prescription Drug Plan rating system.

Given that the overall Medicaid population more closely resembles that of the Marketplace, modeling the quality rating system for Medicaid on that of the QHPs offered through Marketplaces makes the most sense; however, there are some instances in which performance measures from the MA five-star rating system may be appropriate for use for some Medicaid populations, such as dual eligible beneficiaries or individuals in need of LTSS (see *http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/FSQRS.html* for more information on the MA five-star rating system). Alignment with the rating system currently in place for the QHPs offered through Marketplaces would minimize the burden on health plans that operate in both markets and provide data for the various quality rating systems.

The use of a rating system that is consistent in format and scope with those for QHPs in the Marketplaces and MA plans would make it easier for beneficiaries, who may be transitioning among these various coverage programs, to understand the quality rating of their health plan regardless of the payer. Medicaid consumers would also have useful and understandable quality information to assist them in making an informed choice among the health coverage choices available to them in a state. While some states currently operate performance rating systems for Medicaid managed care plans and report publicly on plan performance, this is not the case in all Medicaid programs.

To ensure that states and other stakeholders have ample opportunity to comment and offer feedback during the development of the proposed Medicaid quality rating system, we would utilize a robust public engagement process, similar to that used by CCIIO in the development of the QHP quality rating system. This may include a series of listening sessions or town halls, the release of a request for information, and/or a series of notice and comment periods. Our intention is that the Medicaid managed care quality rating system standards would be refined over a period of three to five years prior to implementation. This would allow CMS time to further identify the respective state and federal roles in

[15] Some of the measures in the QHP Quality Rating System measure set will be collected as part of the QHP Enrollee Experience Survey, which is largely based on items from the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) survey.

implementation and maintenance of the system.

Based on these considerations and desired outcomes, we propose in § 438.334(a)(1) that states establish a rating system that includes specific factors outlined in the rest of the section. We propose in § 438.334(a)(2), that the components of the rating system be based on the same three summary indicators that are currently used to frame the QHP quality rating system (clinical quality management, member experience, and plan efficiency, affordability, and management). In paragraph (a)(3), we propose that the state's quality rating system would measure and report on performance data collected from each MCO, PIHP, and PAHP on a standardized set of measures that will be determined by CMS, through the public notice and comment process and published in the **Federal Register**, as outlined in proposed § 438.330(a)(2). This notice and comment period would allow CMS and the states to jointly identify measures through a multi-stakeholder process that includes Medicaid state partners, representatives of MCOs, PIHPs, and PAHPs, consumer groups, and performance measure experts. This would also enable CMS, the states, and other stakeholders to give consideration to the types of measures that are frequently collected by states, that are reported under other reporting systems, and that are standardized, validated, and appropriate to the types of services provided and populations served by Medicaid health plans. We anticipate that we would propose measures for this purpose and through this process based on considerations such as importance of underlying performance, performance gaps, reliability and validity, feasibility, and alignment. Further, as proposed in paragraph (a)(3), the measures would be categorized within the components proposed in paragraph (a)(1), and the state would be able to adopt additional measures.

Paragraph (b) proposes that each state apply a methodology, also established by CMS under § 438.330(a)(2), to the performance measures described in paragraph (a)(3) to determine the quality rating or ratings of each MCO, PIHP, and PAHP. The methodology would also provide for the use of state-identified measures in determining the quality rating or ratings for each MCO, PIHP, or PAHP. We invite comment on the feasibility of adding flexibility for states to change the way in which a measure is weighted in their quality rating methodology, as we recognize that there is diversity in state quality improvement goals and in the populations served by each state's managed care program. We envision that this measure selection/methodology development process would occur once every 2 to 3 years, to ensure that the selected measures and/or methodology be updated or changed if necessary.

Recognizing the need for state flexibility, we propose in paragraph (c) that, contingent on CMS approval, states may elect to use an alternative or preexisting quality rating system in place of the rating system that we propose in paragraphs (a) and (b) of this new section. This would allow states that have already invested in the development and implementation of their own quality rating system the option of either adopting or modifying the preexisting system. An alternative rating system would potentially utilize different components than those described in paragraph (a)(2), incorporate the use of different performance measures described in paragraph (a)(3), and/or apply a different methodology from that described in paragraph (b).

To avoid duplication of effort, in paragraph (d), we propose providing states with the option to default to the MA five-star rating system for those plans that serve dual eligible beneficiaries only. Finally, in paragraph (e), we propose that states prominently display the results of their quality rating system or systems online in a manner that complies with the language and format standards of § 438.10. This would ensure that beneficiaries have access to the quality ratings to assist them in making choices among health plans. We solicit comment on our proposal for a Medicaid managed care quality rating system, including whether our proposal provides sufficient flexibility for states, ensures enough alignment of Medicaid managed care plans with those operating in the Marketplaces and MA, and provides adequate parameters for the establishment of the quality rating systems.

(f) Comprehensive State Quality Strategy (New § 431.500, § 431.502, § 431.504, § 431.506, and § 438.340)

Under the existing regulation at § 438.202(a), states contracting with MCOs or PIHPs currently maintain a written strategy for assessing and improving the quality of managed care services offered by all MCOs and PIHPs. Regardless of delivery system, it is important to measure performance to develop a plan to strengthen and improve the quality of care. Because of this, we propose adding a new subpart I to part 431 that would extend the comprehensive quality strategy to all state Medicaid programs.

(1) Basis and Scope (New § 431.500)

With recent developments in delivery system reforms and as state health information exchanges become more interoperable with state-based Marketplaces, other payers, and state agencies, we believe each state should have a quality strategy to address and support efforts to strengthen quality in a state's Medicaid managed care program (inclusive of MLTSS programs, where applicable), as well as other types of delivery systems for Medicaid services. Our proposal below integrates guidance contained in the State Health Official letter entitled Quality Considerations in Medicaid and CHIP (SHO #13–007, available at: *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SHO-13-007.pdf*), which explains how to incorporate a state's managed care quality strategy into a larger, statewide comprehensive Medicaid quality strategy. This guidance allows for state flexibility in how to convert an existing quality strategy into a comprehensive document; for example, in some cases, LTSS strategies should be aligned with, but not the same as, acute care strategies.

In § 431.500, we describe the statutory basis and scope of the proposed new subpart I. Our statutory authority to adopt standards for a quality strategy is established in section 1932(c) of the Act for MCOs and based on section 1902(a)(4) of the Act for PIHPs. We rely as well on section 1902(a)(4) of the Act to establish a standard for a comprehensive quality strategy for delivery of services to all Medicaid beneficiaries because such a strategy would promote efficient and proper administration of the state plan as a whole. We also propose to rely on section 1902(a)(6), for purposes of the proposed reporting in § 431.504, which provides that ''the State agency will make such reports, in such form and containing such information, as the Secretary may from time to time require, and comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports''; section 1902(a)(19), which obligates the provision of ''such safeguards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients''; and section 1902(a)(22) which allows CMS to request that states ''include

descriptions of . . . other standards and methods that the State will use to assure that medical or remedial care and services provided to recipients of medical assistance are of high quality.''

In paragraph (b), we propose that the scope of this new section establish parameters for states to develop a comprehensive quality strategy to monitor the delivery of quality health care to Medicaid beneficiaries. This would include states contracting with MCOs, PIHPs, or PAHPs, those utilizing a PCCM arrangement, and those that deliver services through FFS. CMS will provide technical assistance to those states that do not currently contract with MCOs or PIHPs and thus, would need to develop a quality strategy if they have not already done so. We solicit comments on our proposal for a comprehensive quality strategy.

(2) State Comprehensive Quality Strategy (New § 431.502)

The current § 438.202(a) identifies responsibilities for the managed care quality strategy for states contracting with MCOs and PIHPs. Consistent with the goal of supporting quality improvement for all Medicaid delivery systems, in our proposed § 431.502(a) we identify a general rule for state comprehensive quality strategies: All states, regardless of whether they contract with a MCO under section 1903(m) of the Act or another managed care entity under part 438, would draft and implement a written comprehensive quality strategy to assess and improve the quality of health care and services provided to all Medicaid beneficiaries.

In paragraph (b)(1), we propose that the strategy include the state's goals and objectives for continuous quality improvement, which must be measurable and take into consideration the health status of all Medicaid-covered populations in the state. States should take into account a variety of data (such as population health status, service utilization and expenditure information, quality of life issues, quality metrics, etc.) when developing such goals. In paragraph (b)(2), we propose that states identify the specific quality metrics and performance targets that they plan to use to measure performance and improvement; these should be linked to the goals identified in paragraph (b)(1). Existing, validated quality metrics, such as the CMS Medicaid/CHIP Child and Adult core measure sets, may serve as a basis for selecting metrics under this proposed paragraph. CMS will provide technical assistance to help states in determining minimum performance levels and/or appropriate performance targets for each metric. Further, we propose that states annually publish these quality metrics and performance standards on their Web site.

(3) Comprehensive Quality Strategy Development, Evaluation, and Revision (New § 431.504)

In the new § 431.504, we propose to recodify and slightly modify the existing state responsibilities related to the quality strategy in the current § 438.202(b), (d), and (e), expanding the application of these standards to the comprehensive quality strategy and not just the strategy for the managed care program. These state responsibilities include obtaining public input in the development and revision of the quality strategy, an evaluation of the effectiveness of the quality strategy, and submission of the quality strategy to CMS for review. Our proposal carries over much of the substance of the current rule.

In developing the comprehensive quality strategy, we believe that states should continue to work cooperatively with beneficiaries, stakeholders, and other interested parties, to benefit from their knowledge, expertise, and unique perspectives with regard to the delivery of Medicaid services. Stakeholders may possess on-the-ground knowledge that would benefit states in identifying quality improvement goals and selecting the best approach to achieve better health outcomes. Accordingly, we propose in paragraph (a) to add the State Medical Care Advisory Committee and tribes (through tribal consultation), as appropriate, to the existing list of persons and entities from which the state would obtain input when developing the strategy. We propose that this input be obtained prior to submitting the comprehensive quality strategy to CMS, to ensure that stakeholder concerns have been taken into consideration at an early phase in the quality strategy development process.

In paragraph (b), we propose to expand to the comprehensive quality strategy the existing standard that states review and update the document ''as needed'', but replace the word ''periodically'' with a timeframe to update the strategy at least once every 3 years. Currently, some states operate under quality strategies that were drafted more than 5 years ago, and thus may not be reflective of today's programs and populations. We encourage states to view the comprehensive quality strategy as a living document, which should be updated on a regular basis to account for changes in population, delivery system structure, emerging information system technology, and benefit design. We also propose to improve clarity by using ''review and update'' instead of ''conduct reviews . . . and update'' in the regulation text.

In further support of improved clarity, we propose moving the evaluation of the effectiveness of the quality strategy into a new paragraph (b)(1) and, in paragraph (b)(2), we propose that states make the results and findings of this effectiveness evaluation publicly available on the state's Medicaid Web site. The language from the current § 438.202(e)(2) related to the submission of regular reports on the implementation and effectiveness of the strategy would be captured in our proposed § 431.504(b)(1) and (b)(2). To streamline the submission of these regular reports, we propose that states post these on their Medicaid Web site, rather than submitting such reports to CMS as the current regulation states.

In paragraph (c)(1), we propose slightly modifying, for purposes of clarification, the existing language in § 438.202(e)(1) that the state submit a copy of the initial strategy to CMS. We clarify that this submission would be for purposes of receiving CMS comment and feedback before adopting the comprehensive quality strategy in final. In paragraph (c)(2), we propose that states submit a copy of the revised strategy whenever significant changes are made. We also propose that states include their definition of ''significant changes'' within the body of the quality strategy, as this would improve transparency regarding the elements that would trigger a revision of the document.

Finally, in paragraph (d), we propose that states make their final comprehensive quality strategy available on the state's Medicaid Web site. While this is already the practice of many states, this would help to increase transparency of a state's quality development and oversight process, and support our efforts in maintaining an up-to-date library of state comprehensive quality strategies on Medicaid.gov.

(4) Applicability to Medicaid Managed Care Programs (New § 431.506)

To reduce the burden on states contracting with managed care entities and to ensure that the comprehensive quality strategy addresses all populations, we propose to cross-reference the managed care elements of a quality strategy in part 438 that apply to MCOs, PIHP, and PAHPs, as well as PCCM entities described in the proposed § 438.3(r). This section

proposes that states contracting with one of the aforementioned managed care entities would be able to create the managed care quality strategy by incorporating the part 438 elements into the larger, comprehensive quality strategy. We would be available to provide technical assistance to managed care states that shift their existing quality strategy from managed care to a more universal blueprint for quality at the state level.

(g) Managed Care Elements of State Comprehensive Quality Strategies (New § 438.340, Formerly § 438.204)

The current § 438.204 identifies the minimum elements of a managed care state quality strategy, including: (1) MCO and PIHP contract provisions that incorporate the standards in existing subpart D; (2) procedures for assessing the quality and appropriateness of care and services furnished to all enrollees under the contract, providing information about the race, ethnicity and language of beneficiaries to MCOs and PIHPs at the time of enrollment, and regular monitoring and evaluation of MCO and PIHP compliance with the standards in subpart D; (3) specification of any national performance measures identified by CMS; (4) arrangements for annual, external independent reviews of quality outcomes, and timeliness of, and access to, services provided by each MCO and PIHP; (5) appropriate use of intermediate sanctions for MCOs; (6) an information system sufficient to support initial and ongoing operation and review of the state's quality strategy; and (7) standards, at least as stringent as those under the applicable subpart D of the regulations.

Consistent with our proposal in part 431, subpart I, and to more accurately reflect the substance of this section, we propose to title this section ''managed care elements of the state comprehensive quality strategy''. In addition, our proposal to extend the quality strategy to states contracting with PAHPs is reflected throughout the proposed text. We propose to use the existing format of § 438.204 (elements of State quality strategies) and list out the minimum elements related to managed care for inclusion in the state comprehensive quality strategy; however, we propose to remove some of the existing content elements and clarify that these are in addition to the other elements proposed in part 431, subpart I.

In paragraph (a), instead of a reference to the standards in the current subpart D, we propose that states include only their network adequacy and availability of service standards and examples of evidence-based clinical practice guidelines that its managed care plans follow. We believe this would transition states toward defining metrics for assessing improvement strategies rather than simply repeating contractual language. It would also allow stakeholders, including beneficiaries, to understand state-specific access standards without having to refer to the MCO, PIHP, or PAHP contract.

We propose to delete the content of the existing § 438.204(b)(1), as we believe that a description of procedures to assess the quality and appropriateness of care and services furnished to all Medicaid enrollees under the MCO, PIHP and PAHP contract(s) is captured in our proposed part 431 subpart I. We propose deleting reference to the other information currently found in §§ 438.204(b)(2) and (b)(3), as we plan to address this in future guidance related to the comprehensive quality strategy.

In § 438.340(b), we propose that the state's goals and objectives developed under our proposed § 431.502(b)(i) incorporate a description of quality metrics and performance targets that the state will use to assess Medicaid managed care quality, including any performance measures in accordance with our proposed § 438.330(c) and any performance improvement projects in accordance with our proposed § 438.330(d). We believe this standard would take the place of the existing element in § 438.204(c). In the event that the state directs its managed care plans to implement certain interventions when conducting a performance improvement project, we propose they include a description of those interventions within the quality strategy. We believe the provision of this information would help states and their health plans link the selection of measures and improvement projects directly to the state's quality improvement goals and objectives.

We propose redesignating the current § 438.204(d) and (e) to § 438.340(c) and (d), respectively, and to expand the external review element to PAHP contracts as well. We propose to eliminate the text currently found in § 438.204(g), which calls for states to include standards, at least as stringent as those in subpart D, within the quality strategy because we believe this is redundant to the proposed changes we explained in paragraph (a). Finally, in paragraph (e), we propose that states address how they would assess the performance and quality outcomes achieved by each PCCM entity, to conform to other changes made in this part.

(h) External Quality Review (§ 438.350)

In § 438.350, we propose to modify the title of the section that identifies the state's responsibilities related to EQR to clarify that these responsibilities are specific to the EQR process. In addition to proposing the application of EQR to PAHPs, consistent with our proposal discussed in § 438.310, we propose a minor restructuring of § 438.350 and a few substantive changes. We propose to redesignate existing paragraphs (a) through (f) as (a)(1) through (a)(6). In paragraph (a)(3), we propose that information from Medicare or private accreditation reviews is a permissible source of information for use in the EQR, in addition to information gathered from the EQR-related activities as described in § 438.358. We also propose clarification in (a)(4) that the information gathered from each EQR-related activity is for use in the EQR and resulting EQR technical report. Finally, in paragraph (b), we propose to add that if a state chooses to perform an EQR on a PCCM entity, the standards laid out in paragraphs (a)(2) through (6) apply. As mentioned earlier in this proposed rule, based on the range of functions that PCCM entities can provide to states, states may elect to subject (at their option) each PCCM entity—specifically, those with contracts which provide for shared savings or other payment incentives—to the EQR process, but we believe most of the same standards (as used by MCOs, PIHPs, and PAHPs) concerning EQR should apply for reasons mentioned elsewhere in this preamble.

(i) External Quality Review Protocols (§ 438.352)

We are not proposing any changes to § 438.352. This section sets forth the parameters for the EQR protocols. Protocols are detailed instructions from CMS for personnel to follow when performing the EQR-related activities. Protocols must specify: (1) The data to be gathered; (2) the source of the data; (3) the activities and steps to be followed in collecting the data to promote its accuracy, validity, and reliability; (4) the proposed methods for valid analysis and interpretation of the data; and (5) all instructions, guidelines, worksheets and any other documents or tools necessary for implementing the protocol. Under section 1932(c)(2)(A)(iii) of the Act, the Secretary, in coordination with the National Governors' Association, contracts with an independent quality review organization to develop such protocols.

(j) Qualifications of External Quality Review Organizations (§ 438.354)

We propose two modifications to § 438.354, which sets forth the competence and independence standards that an entity must meet to qualify as an EQRO. First, we propose additional text, consistent with our overall proposal, to expand EQR to PAHPs. Second, in paragraph (c)(3)(iv), we propose that an accrediting body may not also serve as an EQRO for a health plan it has accredited within the previous 3 years. This is due to our proposal that an EQRO be allowed use the results of an accreditation review to perform the final EQR analyses; we do not want the financial relationship between a health plan and its accrediting body to influence the results of the EQR (or the information that is included in the resulting EQR technical report). We also propose a corresponding redesignation of existing paragraph (c)(3)(iv) to (c)(3)(v).

(k) State Contract Options for External Quality Review (§ 438.356)

Our proposed revisions to § 438.356 would provide additional clarification to the existing EQRO contracting process. We propose changing the title of this section to clarify that it is specific to EQR contracting. In paragraph (a)(2), we propose adding that other entities, in addition to or instead of an EQRO (such as the state or its agent that is not an MCO, PIHP, or PAHP) may conduct the EQR-related activities to comport with this same flexibility afforded to states in § 438.358. In paragraph (e), we propose the addition of a cross-reference to paragraph (a), with the addition of ''with an EQRO'' to make clear that the contract subject to the open, competitive process is the state's contract with the EQRO. We also, in paragraph (e), propose to update the cross-reference to the part of 45 CFR that governs grants to state governments from part 74 to part 75, to reflect changes that occurred after the existing regulations were finalized.

(l) Activities Related to External Quality Review (§ 438.358)

This section sets forth the activities that produce information that the EQRO must use to conduct the EQR, to draw conclusions regarding access, timeliness, and quality of services provided by managed care plans, and to draft the final EQR technical report. There are currently three mandatory and five optional EQR activities under this regulation. The three mandatory EQR-related activities are: (1) Validation of performance improvement projects; (2) validation of performance measures; and (3) determination of compliance with the standards set forth in subpart D. The five optional activities are: (1) Validation of encounter data; (2) administration or validation of surveys; (3) calculation of additional performance measures; (4) conduct of additional performance improvement projects; and (5) conduct focused studies of quality of care. The current regulation also permits EQROs to provide technical assistance if the state directs. We propose several changes to this section, including the addition of text to be consistent with our proposal to extend EQR to PAHPs.

We propose separating the current paragraph (a) into two paragraphs, the first of which would retain the language in the current general rule. Our proposed paragraph (a)(2) would clarify that the information resulting from the performance of the EQR-related activities would be used in accordance with § 438.350(a)(3) to complete the EQR. In paragraph (b), we propose minor technical changes to make clear that the mandatory activities would be performed for each MCO, PIHP, and PAHP. In paragraphs (b)(1) and (b)(2), we include reference to the proposed CMS-identified measures and PIPs, which would be developed by CMS, in consultation with the states and other stakeholders, through the public process as described in the proposed § 438.330(a)(2). In paragraph (b)(3) we propose that the mandatory compliance review would consist of an evaluation of the MCO, PIHP, and PAHP standards proposed in subpart D, and because we propose moving the quality assessment and performance improvement program standards to subpart E (as described in the proposed § 438.330), we reference that section as well. This does not propose any significant change from what comprises the current compliance review activity.

We propose the addition of a new mandatory EQR-related activity in paragraph (b)(4), the analysis of which would be included in the annual EQR technical report in accordance with § 438.364. This proposed EQR-related activity, would validate MCO, PIHP, or PAHP network adequacy during the preceding 12 months to comply with the state standards developed in accordance with § 438.68. An assessment of compliance with § 438.206 (availability of services) would occur as part of the mandatory compliance review described in § 438.358(b)(3); however, because the methods that are frequently used to do so are limited to the review of policies and procedures and onsite interviews of personnel, we propose that this proposed EQR-related activity would go beyond the compliance activity by directly evaluating and validating network adequacy on an annual basis. While the specifics of this activity would be identified in a new EQR protocol, we envision the inclusion of steps such as measurement of how effectively a plan is meeting a state's specific access standards (for example, time and distance standards), direct testing to determine the accuracy of network information maintained by health plans, and telephone calls to providers that either assess compliance with a specific standard, such as wait times for appointments, or assess the accuracy of provider information, such as whether a provider is participating in a plan.

Finally, in paragraph (d), we propose a minor technical change by clarifying that technical assistance may be provided by the EQRO to assist health plans in conducting activities that would produce information for the resulting EQR technical report.

(m) Non-Duplication of Mandatory Activities (§ 438.360)

This section is based on section 1932(c)(2)(B) of the Act, which provides the option for states to exempt health plans from EQR-related activities that would duplicate activities conducted as a part of a Medicare review conducted of an MA plan or a private accreditation survey. To avoid duplication of work, the state may currently use information about contracted MCOs or PIHPs that is obtained from a Medicare or private accreditation review to provide information otherwise gathered from performing the mandatory EQR-related compliance review, but not for the validation of performance measures or PIPs. In addition, for plans that exclusively serve dual eligible beneficiaries, states may use information obtained from the Medicare program in place of information otherwise gathered from performing the mandatory EQR-related activities of validating performance measures and validating PIPs.

We propose giving states the option to rely on information obtained from a review performed by Medicare or a private accrediting entity in lieu of performing the three existing mandatory EQR-related activities: (1) The validation of PIPs, (2) the validation of performance measures, and (3) the compliance review. The purpose of this proposal is to prevent duplication of effort for the three EQR-related activities. For example, MCOs that are accredited by NCQA already collect the performance measurement data known

as HEDIS® measures, and part of the NCQA accreditation process is for one of its approved vendors to validate the statistical accuracy of the data. If the measure validation process used by the approved vendor is consistent with guidance in the CMS EQR protocol on the validation of performance measures, and each accredited plan submits their most recent accreditation results to the state, at the state's option the state or its agent would no longer have to perform the mandatory EQR-related activity of performance measure validation. However, the state would still provide the results of the accreditation survey to the EQRO, so that the EQRO could perform an analysis and aggregation of data to satisfy the deliverables described in § 438.364.

To effectuate these changes and to clarify the regulatory language, we propose in paragraph (a) that the state may use information about an MCO, PIHP, or PAHP obtained from a Medicare or private accreditation review within the past 3 years in place of the information that would be obtained by completing one or more of the three existing EQR-related mandatory activities. We do not propose extending this option for non-duplication to the fourth, newly proposed EQR-related mandatory activity for validation of network adequacy, as we do not yet know the scope of what this newly proposed activity will entail or how well it would line up with current accreditation standards.

Because of our proposal to extend the non-duplication option to three mandatory activities, we propose to combine and streamline the content in the current § 438.360(b) and (c), as it would no longer be necessary to separately address plans serving only dual eligibles. In paragraph (b)(1), we propose clarifying that the Medicare or private accreditation review standards must be substantially comparable to the standards for the three EQR-related activities to be eligible for non-duplication. The reason for this is that the information obtained should be similar enough to that which would be obtained through an EQR-related activity so that the state's EQRO would be able to effectively perform an analysis in accordance with § 438.364, as we specify in the proposed paragraph (b)(2).

Finally, we retain that states identify whether they opt to deem any of the EQR-related activities under this option, and include the reasons for doing so, in the comprehensive quality strategy. This redesignates the current § 438.360(b)(4) and (c)(4) to paragraph (c).

(n) Exemption From External Quality Review (§ 438.362)

This section is based on section 1932(c)(2)(C) of the Act, which provides that a state may exempt a health plan from undergoing an EQR if the MCO has a current Medicare contract under part C of Title XVIII or under section 1876 of the Act, and, for at least 2 years, has had in effect a Medicaid contract under section 1903(m) of the Act. We propose the removal of PIHPs, as they are not entities that fall under section 1903(m) of the Act. We also propose to update the phrase ''Medicare+Choice'' to ''Medicare Advantage''.

(o) External Quality Review Results (§ 438.364)

This section sets forth the information, or final deliverables, that annually result from the EQR. We propose several changes to this regulation to assist CMS and the states in meaningfully assessing the performance of each health plan. Currently, the EQR activities in § 438.358(b)(1) and (2) only refer to validation of the data. While we continue to believe that data validation is important and should remain a core function of the EQR process, a statement of validation alone is insufficient to provide insight into plan performance on quality, timeliness, and access to care. Therefore, under § 438.364(a)(1) we propose that each EQR technical report include performance measurement data for any collected performance measures and implemented PIPs (in accordance with each EQR activity conducted in accordance with § 438.358(b)(1) and (2)). There are several benefits from modifying the EQR technical report, particularly in combination with a standardized sub-set of EQR topics and measures. First, public reporting on a common set of measures would align with the approach used by Medicare and the Marketplace to monitor and support continuous quality improvement. Second, displaying the performance results of these common measures would allow beneficiaries and stakeholders to compare the quality of care across health plans. Finally, sharing this information publicly would allow states to learn best practices from one another and reveal lessons learned in dealing with challenges faced by states and plans when engaged in quality measurement and improvement.

In paragraph (a)(3), we propose the inclusion of recommendations for how states can target the goals and objectives in the comprehensive quality strategy to better support improvement in the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries. In paragraph (a)(4), we propose deleting the language that allows the state alone to decide the appropriate methodology of comparative information about managed care plans, as we believe this should be a determination made by the state in conjunction with CMS (via the Protocols, as described in § 438.352).

In paragraph (b)(1), we propose that states contract with a qualified EQRO to produce the final EQR technical report (that is, we clarify that there is no other entity which may produce the EQR technical report) and we propose that this report be completed and available for public consumption no later than April 30th of each year. An April 30th submission date would align with the timeframe needed for the collection and annual reporting of managed care data by the Secretary each September 30th as prescribed by section 401 of CHIPRA and section 2701 of the Affordable Care Act. We also propose in this same paragraph that states may not substantively revise the content of the final EQR technical report without evidence of error or omission, or upon requesting an exception from CMS. Allowing states to substantively alter information in the EQR technical report could possibly result in a departure from the original statutory intent for the performance of an external, independent review.

Paragraph (b)(2) proposes that states maintain the most recent copy of the EQR technical report on the state's Medicaid Web site, proposed under § 438.10(c)(3). We believe this would serve to facilitate public access to the EQR technical reports. This would also allow CMS to directly link the reports to the Medicaid.gov Web site, thus creating a comprehensive library of state EQR technical reports. We also propose to separate out the existing language for states to make the information available in alternative formats for persons with disabilities in a new paragraph (b)(3). As part of this proposal, we replace the phrase ''sensory impairments'' with ''disabilities''.

(p) Federal Financial Participation (§ 438.370)

This section sets forth the matching rates for expenditures for EQR, including the production of EQR results and the conduct of EQR-related activities when performed by a qualified EQRO or other entity. The changes proposed in this section mark a departure from previous interpretation of the entities eligible for the enhanced 75 percent EQR match rate as found in

section 1903(a)(3)(C)(ii) of the Act. In the 2003 final rule, CMS used the authority of section 1902(a)(4) of the Act to extend EQR to PIHPs. We determined that, because we were extending the performance of EQR under section 1932(c)(2) of the Act to PIHPs, such review could be considered to be performed ''under'' section 1932(c)(2) of the Act, even though it was not ''required'' by section 1932(c)(2) of the Act itself for purposes of qualifying for the enhanced federal match rate of 75 percent. Upon closer examination of the applicable statutory language, we have reconsidered that interpretation and now believe the reference in section 1903(a)(3)(C)(ii) of the Act to review ''under'' section 1932(c)(2) of the Act should be construed to refer to review ''required'' by that section. Therefore, we propose in paragraph (a) that only EQR or EQR-related activities performed by EQROs for MCOs with contracts under section 1903(m) of the Act are eligible for the 75 percent match.

In paragraph (b), we propose clarifying that EQR and EQR-related activities performed on entities other than MCOs (including PIHPs, PAHPs, primary care case management arrangements, or other types of integrated care models) would be eligible for a 50 percent administrative match, regardless of what type of entity performs the review (that is, the state, its agent that is not an MCO, PIHP, or PAHP, or an EQRO).

Finally, in paragraph (c), we propose that states submit their EQRO contracts to CMS prior to claiming the 75 percent match. Although section 1932(c)(2) of the Act does not require review and approval by CMS of EQRO contracts, we believe the reason for doing so remains the same as it is today—to allow CMS to determine if the EQRO contract complies with the EQR-related provisions of this rule (for example, by confirming that contracting entities meet the standards set forth in § 438.354 for qualified EQROs), and, if so, which activities under the contract are eligible for the 75 percent match.

c. State Monitoring Standards (§ 438.66)

Experience since the 2002 final rule has shown that strong state management and oversight of managed care is important throughout a program's evolution but is particularly critical when states transition large numbers of beneficiaries from FFS to managed care or when new managed care plans are contracted. We have observed that states must train and deploy staff or utilize vendors to verify that plans have sufficient provider capacity to serve new enrollees, are ready to pay provider claims accurately and on time, can respond promptly to enrollee complaints and problems, and have IT systems that can receive and generate state data and reports. Further, when a managed care plan contracts with the state for the first time, states need time to conduct readiness reviews.

We are proposing modernization of state monitoring standards. We rely on the authority in section 1902(a)(4) of the Act for the proper and effective operation of the state plan to strengthen our existing regulation at § 438.66, noting that many of these practices are employed by states today. We begin by proposing a minor change in the title of this regulation section to clarify that the monitoring required here is a state activity.

In paragraph (a), we propose that the state have a monitoring system for all of its managed care programs; we intend the term monitoring to include oversight responsibilities. In paragraph (b), we propose that the state's monitoring system address, at a minimum, specific aspects of the managed care program that include: Administration and management; appeal and grievance systems; claims management; enrollee materials and customer services; finance, including medical loss ratio reporting; information systems, including encounter data reporting; marketing; medical management, including utilization management; program integrity; provider network management; quality improvement; the delivery of LTSS; and other items of the contract as appropriate. Research has highlighted these program areas as critical for state success. See, for example, the research report by the AARP Public Policy Institute titled ''Keeping Watch: Building State Capacity to Oversee Medicaid Managed Long-Term Services and Supports'' [16] (July 2012).

In § 438.66(c), we propose that states use data collected from its monitoring activities to improve the performance of its managed care program. While we expect that many states already take this approach, we propose to set it out here as a baseline standard for all managed care programs. In this section we provide a list of activities for which data should be used for performance improvement. This list encompasses the areas that we believe are fundamental to every managed care program and for which data is readily available. We do not propose an exhaustive list in § 438.66(c) of the performance areas about which data should be used in improvement efforts to provide flexibility for the state to collect and use additional data they find useful and pertinent for its program.

In § 438.66(d), we propose to establish a new standard for states to conduct readiness reviews of MCOs, PIHPs, PAHPs and PCCM entities prior to the effective date of new or modified managed care programs, although experience has shown that states employ this practice today. As proposed in paragraph (d)(1)(i) through (iv), readiness reviews would have to be conducted prior to the start of a new managed care program; when a new contractor enters an existing program; or when the state adds new benefits, populations or geographic areas to the scope of its contracted managed care plans. We propose in paragraph (d)(2)(i) and (ii) that these readiness reviews would have to be started at least 3 months before the State implements any of those program changes, so that states ensure that critical MCO functions are operational far enough in advance for successful implementation. In paragraph (d)(2)(iii), we propose that the results of those readiness reviews would have to be submitted to us to enable us to determine if the contract or contract amendment is approved. This would permit both CMS and the state to review the findings, discuss any possible issues, and arrive at a mutual understanding of expectations. In paragraph (d)(3), we propose that the readiness reviews would consist of both a desk review of documents and an on-site visit that includes (at a minimum) interviews with staff and leadership that manage key operational areas. We do not propose to define the key operational areas but rely on states to reasonably identify those areas in light of the areas which are identified in proposed paragraph (d)(4). We believe these are customary in readiness reviews of this kind and have proven effective in helping states gather all of the information needed. Finally, proposed paragraph (d)(4) would require four broad areas for inclusion in the readiness review and outline sub-components within each area. The broad areas are: (1) Operations and administration; (2) service delivery; (3) financial management; and (4) systems management. While a state can add more areas to their review, we believe these provide a minimum foundation from which to build an effective readiness assessment.

We note that these standards reflect our current guidance. For example, our guidance for MLTSS programs under

[16] *http://www.aarp.org/health/medicare-insurance/info-07-2012/keeping-watch-building-state-capacity-to-oversee-medicaid-managed-long-term-services-and-supports-AARP-ppi-health.html.*

section 1915(b) waivers and section 1115(a) demonstration projects set forth MCO readiness to implement LTSS as a key element under adequate planning; likewise under Special Terms and Conditions for new or expanding managed care programs under these waiver and demonstration authorities, states conduct readiness reviews of their contracted managed care plans. Health plans participating in the Capitated Financial Alignment Demonstration have to undergo an extensive readiness review process before contracts will be signed and enrollment of dual-eligible beneficiaries will be permitted.

Finally, to address the fragmented program information we currently receive about states' managed care programs and to help improve our oversight efforts, we propose in § 438.66(e) that states provide an annual program assessment report to us. States would have to submit these to us no later than 150 days after the end of the managed care plan's period of performance; this is intended to provide flexibility to states which operate their programs on calendar year, state fiscal year, or some other basis. We request comment on whether 150 days is enough time after the end of a program year for the state to provide the type of information we are proposing. In (e)(1), we propose flexibility for states which already have to provide an annual report under section 1115(a) demonstrations to submit that report for this purpose if the information in the annual report is duplicative of the information specified here.

We outline in proposed paragraph (e)(2) the areas on which information and an assessment would have to be submitted by the state in the report. We propose that the report include information about, and assessments of the 8 areas of the managed care program detailed in paragraph (b)(2). We take the opportunity here to emphasize that states providing LTSS through managed care plans would also have to include areas specific to MLTSS in this assessment; these could include alignment of payment rates and incentives/penalties with the goals of the program, any activities the managed care plans have undertaken to further the state's rebalancing efforts, and the satisfaction of enrollees with their service planners. In (e)(3), we also propose that this annual program assessment would have to be posted publicly and provided to the Medical Care Advisory Committee and, if applicable the LTSS stakeholder group specified in § 438.70.

d. Information Standards (§ 438.10)

We are concerned that current § 438.10 pertaining to information standards is not sufficiently clear or direct and does not reflect current technology advances that provide access to information more quickly and less expensively. For that reason, we propose to replace the entire existing regulation section with a more structured and coherent set of state and managed care plan standards for beneficiary information. Electronic communications are becoming typical, and we propose to explicitly permit both states and managed care plans to make beneficiary information available in electronic form. Electronic information will need to be disseminated in a manner compliant with Section 504 of the Rehabilitation Act. In addition, we believe that this proposed acceptance of electronic information delivery would further our goal of alignment across insurance affordability programs by aligning Medicaid managed care beneficiary information dissemination practices with those of the MA program and the commercial insurance market. We note that in this proposed rewrite of § 438.10, we have removed the distinctions among MCO, PIHP and PAHP information standards. We believe that regardless of the scope of the managed care plan's benefits, the information that should be provided to potential enrollees and enrollees is the same for all types of plans. Consequently, the standards for MCO, PIHP, and PAHP enrollee handbooks, provider directories, and formularies must be consistent. States retain the flexibility—within the minimum federal elements—to tailor the information as needed; for example, specific benefit explanations for potential enrollees can be provided consistent with the scope of the managed care program and contracted managed care plans.

We propose to move the current definitions in paragraph (a) to § 438.2 because those terms (''potential enrollee'' and ''enrollee'') are used throughout this part. It is important, however, to note the differences in these definitions: ''Potential enrollee'' refers to a beneficiary that has been determined eligible for Medicaid but is not yet enrolled in a managed care plan, while ''enrollee'' refers to a beneficiary who is a member of a specific MCO, PIHP, PAHP, PCCM or PCCM entity. Proposed paragraph (a) would revise the definition of ''prevalent'' and add a definition of ''readily accessible'' for use in this section. The term ''prevalent'' is currently defined in § 438.10(c)(1); we propose to amend the current definition of ''prevalent'' to clarify that the non-English languages that are relevant are those spoken by a significant number or percentage of potential enrollees and enrollees in the state that are limited English proficient, consistent with standards used by the Office for Civil Rights in enforcing anti-discrimination provisions related to individuals with limited English proficiency.

We propose to add a definition of ''readily accessible'' to clarify parameters for the provision of electronic information. States, MCOs, PIHP, PAHPs, and PCCM entities should consult the latest section 508 guidelines issued by the U.S. Access Board or W3C's Web Content Accessibility Guidelines (WCAG) 2.0 AA (see *http://www.access-board.gov/sec508/guide/index.htm* and *http://www.w3.org/TR/WCAG20/*) for additional information. We believe it is important to specifically address this issue given the inclusion of more complex populations in managed care programs.

Proposed paragraph (b) would clarify that the standards in this section apply to all managed care programs regardless of authority. We propose this scope deliberately because the distinctions among managed care programs that operate under the state plan and waivers or demonstration projects are immaterial for purposes of beneficiary educational materials that are provided in a managed care program. This proposed rule incorporates those statutory standards of section 1932(a)(5)(B) through (D) of the Act and proposes to expand upon them to encompass additional information for all beneficiaries based on our authority under section 1902(a)(4) of the Act to adopt standards and standards that are necessary for the proper and efficient operation of the state plan.

Proposed paragraph (c) lays out basic standards for information in managed care programs. Several of the proposed standards (that is, paragraphs (c)(1) through (c)(5)) are applicable to the state as part of its responsibility for ensuring delivery of critical program information to beneficiaries. Proposed paragraphs (c)(1), (c)(6) and (c)(7) are applicable to MCOs, PIHPs, PAHPs, and PCCM entities; however, PCCMs would need to comply only with paragraph (c)(1).

In proposed paragraph (c)(1), we state the fundamental standard that each state, enrollment broker, MCO, PIHP, PAHP, PCCM and PCCM entity provide all information in an easily understood and readily accessible manner and format, which includes the use of TTY/TDY and American sign language interpreters; this is similar to the current

regulation at § 438.10(b)(1) but would add PCCM entities consistent with our proposal discussed in section I.B.6.e. of this proposed rule. Except for PIHPs and PAHPs, this language implements the statutory provision in section 1932(a)(5)(A) of the Act for all enrollment, informational and instructional materials. We would rely on section 1902(a)(4) of the Act authority to extend such standards on PIHPs, PAHPs, and PCCMs for the proper and efficient operation of the State plan to ensure that enrollees and potential enrollees receive information in a form and manner that they can understand. In paragraph (c)(2), we propose that states would need to use the beneficiary support system proposed under § 438.71 in this proposed rule to provide education and choice counseling to all beneficiaries. We believe that this cross-reference more clearly expresses what states should do than the current regulation text. Currently in § 438.10(b)(2), states must have in place a mechanism to help enrollees and potential enrollees understand the managed care program. We propose in paragraph (c)(3) that states, as noted earlier in this proposed rule, would need to operate a Web site for information about the state's managed care program. We are confident that all states already operate a Web site and that this proposal would merely codify existing practices. Proposed paragraph (c)(4) would have states develop standardized managed care definitions and terminology, and model enrollee handbooks and notices for use by its contracted managed care plans. The suggested list of definitions and terminology has been adapted from the standards for a uniform glossary that commercial insurers must include as part of their summary of benefits and coverage (SBC) in 45 CFR part 147. Model handbooks and enrollee notices are already used by mature managed care programs that have been in operation for several years and have proven to be a good tool for ensuring consistent information and tone in enrollee communications across a variety of managed care plans. In paragraph (c)(5), states would need to ensure, through their managed care contracts, that MCOs, PIHPs, PAHPs, and PCCM entities provide the information outlined in this section.

Proposed paragraph (c)(6) lists the standards for providing information electronically. Specifically, electronic information would have to be compliant with all language, formatting, and accessibility standards; be in a prominent place on the state's, MCO's, PIHP's, PAHP's, or PCCM entity's Web site; and be able to be retained and printed. Additionally, all information must be made available to enrollees and potential enrollees in paper format upon request at no cost and provided within 5 calendar days. These standards are consistent with those for QHPs operating in the Marketplace; thus we believe that by proposing them we further our goal of alignment across insurance affordability programs.

Proposed paragraph (d) addresses federal standards for the language and format used for beneficiary information, and largely carries over existing standards from current paragraph (c). However, we are proposing to add three new standards, which we believe are important beneficiary standards and recognize the cultural and linguistic diversity of Medicaid beneficiaries. The first two changes, proposed in paragraph (d)(2) and (d)(3), would have materials for potential enrollees disseminated by the state, as well as enrollee materials disseminated by MCOs, PIHPs, PAHPs or PCCM entities, to be available in prevalent languages and include taglines in each prevalent non-English language and large print explaining the availability of written materials in those languages as well as oral interpretation in understanding the materials. We also propose, based on guidance from the American Printing House for the Blind, Inc., that large print must be no smaller than 18 pt. We also propose in (d)(3) that written materials must also be made available in alternative formats and auxiliary aids and services should be made available upon request of the potential enrollee and enrollee at no cost. The third change is proposed in paragraph (d)(3)(i) where we more specifically identify the 'materials' which each MCO, PIHP, PAHP or PCCM entity would have to make available in each prevalent non-English language in its service area. To determine the types of materials to which this standard should apply, we consulted guidance provided by HHS regarding access to programs and services for persons with LEP: HHS Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons 68 FR 47,311 (Aug. 8, 2003) and Executive Order 13166, ''Improving Access to Services for Persons with Limited English Proficiency'' at *www.lep.gov*. The HHS Guidance urges recipients of federal financial assistance, such as Medicaid agencies, to ensure that vital documents are translated into the non-English language of each regularly encountered LEP group eligible to be served or likely to be affected by the program or activity. Vital documents are those which contain information that is critical for obtaining benefits. We are proposing that provider directories, member handbooks, appeal and grievance notices and other notices that are critical to obtaining services be considered vital documents, and therefore would have to be made available in each prevalent non-English language in its service area. The current standard for oral interpretation services would remain mostly unchanged in paragraphs (d)(4) except for adding a clarification that interpretive services include the use of auxiliary aids such as TTY/TDY and American sign language. Currently, under paragraphs (b)(5)(i) and (ii), states have to notify enrollees of the availability of interpretation and translation services and how to access them. We propose to add a new (d)(5)(ii) clarifying that potential enrollees and enrollees must be also be notified that auxiliary aids and services are available upon request and at no cost for enrollees with disabilities. This proposed addition would clarify that interpretive services are not limited to limited English proficient potential enrollees and enrollees. We propose to redesignate current paragraph (d)(5)(ii) as (d)(5)(iii). We request comment on the provisions of this paragraph.

Paragraph (d)(6) includes a standard that the availability of alternative formats for beneficiary materials must include a large print tagline and information on how to request auxiliary aids and services, including the provision of materials in alternative formats. Auxiliary aids would include but are not limited to the use of TTY/TDY and American Sign Language interpreters. We also propose, based on guidance from the American Printing House for the Blind, Inc., that large print must be no smaller than 18 pt. We believe that the proposed changes in paragraph (d) represent important protections for beneficiaries who have limited English proficiency or need materials in other formats due to disabilities to adequately understand managed care programs and successfully navigate managed care plan processes.

In paragraph (e), we propose the information that must be provided to potential enrollees. As this information is provided to beneficiaries who either have the choice to enroll in the managed care program or must be enrolled in the managed care program to receive Medicaid benefits, we believe that it is important for the State to provide

enough information for beneficiaries to know and understand the implications of participating in the managed care program. It is also important, for purposes of making an active selection of a MCO, PIHP, PAHP or PCCM entity, that the potential enrollee receive information about each choice available, including service area, participating providers, and quality and performance information to the extent available. We propose in paragraph (e)(1) to provide flexibility to the states to provide this information in paper or electronic format to ease the administrative burden and cost of mailing paper materials to potential enrollees. Interpretation of our current regulations, which did not provide alternatives to paper, has resulted in compliance actions against states that did not give these materials to potential enrollees in paper. States and MCOs are expected to assure effective communications consistent with the ADA and Section 504 of the Rehabilitation Act, consistent with applicable DOJ guidance. (See: *http://www.ada.gov/effective-comm.htm*), and at a minimum provide auxiliary aids and services to consumers with disabilities who need this information in alternative formats, upon request. We request comment on the flexibility offered to the state on both the information elements and the provision of this information electronically or on paper. Proposed paragraphs (e)(1)(i) and (ii) would maintain current timeframes for the provision of the information.

In paragraphs (e)(2)(i) through (x), we propose a minimum list of topics that the state would need to provide in the information they send to potential enrollees; this includes disenrollment rights, basic features of managed care, populations excluded from enrollment, service area of each manage care plan, covered benefits, provider directory information, cost sharing, network adequacy standards, care coordination services available, and quality indicators for each MCO, PIHP, PAHP, and PCCM entity.

The next paragraphs of proposed § 438.10 focus exclusively on information standards for managed care plan enrollees—that is, once they have selected and enrolled in a managed care plan. Paragraph (f) proposes general standards for both the state and managed care plans regarding enrollee information; paragraph (g) proposes the minimum content of enrollee handbooks and paragraph (h) proposes the minimum content of provider directories. The products of the standards proposed in these paragraphs would provide enrollees with a substantial and valuable source of information on most aspects of how to access care and fully utilize the benefits of their managed care enrollment. These documents, whether electronic or hard copy, offer the enrollee an easy to use reference that can often provide the information they seek. The proposed language in these paragraphs incorporates elements from the current regulatory standards for commercial insurers in 45 CFR part 147 regarding the provision of its SBC. While we recognize that electronic communication is easier and less expensive, we remain concerned that electronic communication not be the sole method for communicating this critical information to enrollees. To that end, we provide flexibility for a range of communication methods, including mail, email, and Web site posting; however, managed care plans would need to notify enrollees that these materials are available in paper form and through auxiliary aids and services at no cost upon request.

As proposed, paragraph (f) would set forth basic standards applicable to information that must be disclosed to enrollees of MCOs, PIHPs, PAHPs, and PCCMs. In proposed § 438.10(f)(1), we propose to redesignate an existing regulatory standard in current § 438.10(f)(5); that standard is that the managed care entity must make a good faith effort to provide notice of the termination of a contracted (that is, in-network) provider to each affected enrollee within 15 days of receipt or issuance of the termination notice. For purpose of these standards, an affected enrollee is one who received his or her primary care from the provider or was seen on a regular basis by the provider. In paragraph (f)(2), we propose to redesignate an existing regulatory standard in current § 438.10(f)(1); the state must notify all enrollees of their right to disenroll and clearly explain the process for doing so and, if enrollment is restricted for 90 days or more, provide this notice at least 60 calendar days in advance of each enrollment period. We propose to add ''calendar'' to remove ambiguity. Lastly, in proposed paragraph (f)(3), MCOs, PIHPs, PAHPs, and when appropriate PCCM entities, would have to provide any physician incentive plans in place as specified in § 438.3(i), upon request.

The regulatory standards in proposed paragraphs (g), (h), and (i) address enrollee handbooks, provider directories, and formularies because we believe these are foundational tools to help enrollees utilize the benefits and services available to them from their managed care plan. Since the majority of Medicaid beneficiaries use managed care plans to access covered benefits, we believe it is critical for enrollees to have the information necessary to understand their rights, maximize their benefits, and be an effective self-advocate when necessary. We have declined to propose regulatory standards for other types of plan-enrollee communications, recognizing that those decisions are best made at the state level based on the maturity and structure of each state's managed care program.

Proposed paragraph (g) outlines minimum content standards for the enrollee handbook and we have attempted to align with commercial insurance standards by reflecting similarities to the SBC in both content and appearance. In proposed paragraph (g)(1), each MCO, PIHP, PAHP or PCCM entity would have to provide an enrollee handbook to each enrollee within a reasonable time after receiving the enrollment notice from the state. While the information proposed to be included in the handbook (in proposed paragraph (g)(2)) already exists in current § 438.10, it is currently not well organized or all in one section for easy reference. Paragraph (g)(2) proposes to compile all of the existing elements in one paragraph for easy reference. Taken together, these elements will be referred to as a ''handbook'' consistent with how the term is typically used in Medicaid managed care. While some minor grammatical revisions have been made for clarity, the elements remain the same as in current regulation. Paragraph (g)(3) proposes to clarify the circumstances under which the MCO, PIHP, PAHP, or PCCM entity would be considered to have provided the information in paragraph (g)(2). We propose mail, email if enrollee consent obtained, Web site with paper and electronic notification, auxiliary aids and services at no cost (upon request), and any other method that can reasonably be expected to result in the enrollee receiving the information. We propose this last method to provide flexibility for communication methods not commonly used, such as alternative communication devices for persons with disabilities, and other technological advances in communication not yet widely available. Proposed paragraph (g)(4) continues the current standard that enrollees be notified 30 days in advance of any significant change to any of the information in paragraph (g). This is an important enrollee protection as it allows the enrollee, if impacted, time to seek additional information or assistance and make appropriate decisions. Consistent with other

proposed revisions throughout § 438.10, we propose to delete the standard that this notice be written and let the provisions of paragraphs (c) and (d) control regarding the standards for the use of written and electronic communications. Proposed paragraph (h) specifies the minimum content standards for provider directories. The content and accuracy of provider directories has long been an issue of contention between states, managed care plans and stakeholders. The move to electronic provision of this document would improve the accuracy of the information; however, even Web-based provider directories can be out of date quickly without accurate information from participating providers to the managed care plans. Additionally, there is wide variation in the information provided in managed care plan provider directories. While we recognize that our proposed elements may not address every type of information that may be helpful for enrollees, we have attempted in this paragraph to balance all perspectives as well as recognize that managed care plans provide member services call centers and auxiliary aids and services (including TDY/TTY lines) which can provide more personalized and timely assistance to enrollees in locating appropriate providers.

Proposed paragraph (h)(1)(i) through (viii) would include all of the elements that exist currently in § 438.10(f)(6)(i) but expands on them in four key ways. In addition to name, address, telephone number, and open panel status, we propose to add four additional elements: A provider's group/site affiliation, Web site URL (if available), the provider's cultural and linguistic capabilities, and the accessibility of the provider's office to enrollees with physical disabilities. Physicians' affiliation with a group/site would assist enrollees in more quickly identifying physicians they are searching for; likewise, a group practice/site Web site can be a good source of information for enrollees. Finally, accommodations available for persons with physical disabilities as stipulated by the Americans with Disabilities Act and Section 504 are critical for managed care plans, which increasingly provide services to individuals with disabilities. This is important both operationally so that enrollees with limited vision and other impairments can reasonably access that information online as well as on paper, as well as in the delivery of services. It also is important for deaf and hard of hearing enrollees who may need in-person ASL interpreters as well as the use of TTY/TDY lines and/or relay services. We believe that meaningful access for those enrollees is available only when they can utilize the full scope of services at a provider's office. We request comment on these new elements, which deviate from the elements that are generally included in provider directories provided by MA plans and group health and private insurers. Paragraph (h)(2)(i) through (v) proposes five provider types that would have to be included in the directory, if applicable under the contract: Physicians, hospitals, pharmacies, behavioral health, and LTSS. In paragraph (h)(3) we propose that paper provider directories must be updated at least monthly and electronic directories within 3 business days of receiving updated provider information. Lastly, to align managed care with both QHPs and MA, in paragraph (h)(4), we propose that provider directories be made available on the MCO's, PIHP's, PAHP's, or if applicable, PCCM entity's Web site. The current rule for MA plans (§ 422.111(h)) requires such plans to post provider directories online. In a recent final rule (80 FR 10873), HHS finalized a requirement for QHPs in a federally facilitated Marketplace to post provider directories in a machine readable format specified by the Secretary. The purpose of establishing machine readable files with provider directories would be to provide the opportunity for third parties to create resources that aggregate information on different plans. We believe posting machine readable formats of directories will increase transparency by allowing software developers to access this information and create innovative and informative tools to help enrollees better understand the availability of providers in a specific plan. Therefore, we are proposing here that MCOs, PIHPs, PAHPs, and if applicable, PCCM entities must post provider directories on their Web sites in a machine readable file and format specified by the Secretary. We invite comment on this proposal.

Going forward, we believe that the accuracy and usefulness of provider directories could be improved by requiring that their data be held in a standardized format and be exposed through open and standardized application programming interfaces (APIs). Specifically, we are considering requiring the best available provider directory standard as listed in the ONC draft of the ''2015 Interoperability Standards Advisory'' published for public comment (available at *http://healthit.gov/standards-advisory*); that advisory lists the IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation Profile. This would allow CMS, State Medicaid, or private third parties to ''plug into'' the provider directories to perform automated accuracy checks. This could be done by comparing the directories against other data sources with bidirectional connections and interfaces, such as death registries and licensure registries. Provider directories with standardized APIs could also be leveraged by developers to create applications that are more useful for consumers than static, non-standardized Web sites. We invite comments on this strategy.

We also propose a new paragraph (i), Information for all enrollees of MCOs, PIHPs, PAHPs, and PCCM entities—Formulary. This proposed paragraph would have MCOs, PIHPs, PAHPs, and PCCM entities provide their medication formularies electronically or paper, if requested. Under proposed paragraph (i)(1) and (i)(2), the formulary must display all covered medications, both generic and brand name, and have the tier of each medication. We are proposing this paragraph because understanding how medications are covered by the managed care plan is important information for enrollees, particularly for those with chronic conditions or on-going needs. Additionally, we propose that formulary drug lists be made available on the MCO's, PIHP's, PAHP's, or if applicable, PCCM entity's Web site in a machine readable file and format as specified by the Secretary for the same reasons discussed in this section of this proposed rule in connection with provider directories. Machine readable files with formulary drug lists would provide the opportunity for third parties to create resources that aggregate information on different plans. We believe this will increase transparency by allowing software developers to access this information and create innovative and informative tools to help enrollees better understand formulary drug lists across specific plans. We invite comment on this proposal.

e. Primary Care Case Management (§ 438.2, § 438.3, § 438.330, § 438.340, and § 438.350)

Primary Care Case Manager (PCCM) services have a unique status in the Medicaid program. PCCM services are considered a State-plan covered benefit through section 1905(a)(25) of the Act. Section 1905(t) of the Act defines PCCM services, the providers that may furnish them, and the standards for a PCCM contract—one of which is that the State's contract with the PCCM complies with applicable sections of

1932 of the Act (the managed care rules in the Act). A primary care case manager, as defined in section 1905(t)(2) of the Act, is considered a managed care entity under section 1932(a)(1)(B)(ii) of the Act. Current regulatory standards in part 438 have minimal standards that PCCM programs have to meet; they generally mirror the statutory standards specified in section 1932 of the Act.

Current regulations reflect the prevailing PCCM program design that existed in 1998. At that time, virtually all PCCM programs were intended to layer a 'gatekeeper' model on top of states' FFS programs. Each primary care provider who acted as a PCCM was paid a small monthly fee (typically less than $5.00) per beneficiary in recognition of the provision of PCCM services, in addition to any direct service payment the provider might also receive from the state, to coordinate access to primary care services and manage referrals to specialty care for Medicaid beneficiaries. The Medicaid provider was not held accountable for quality or health outcomes for that enrollee. We believe the current regulatory structure still works reasonably well for these 'gatekeeper' PCCM programs, which generally are very small and remain exclusively focused on individual primary care providers.

Over the past 8 years, however, states have determined that they need additional tools to better manage utilization of Medicaid services. Some states have added a more intensive care coordination function to their PCCM programs and these care coordination/case management activities have generally been provided, under contract, with regional non-profit networks in some states or for-profit organizations in others. Such entities typically oversee the case management/care coordination activities performed by the primary care case managers and administer provider financial incentives, provider profiling, and performance and quality reporting. The activities performed by the broader entity and the additional responsibilities and incentives available to primary care case managers built upon the early PCCM model; therefore, this expanded approach to primary care case management has been generally referred to as the ''enhanced'' PCCM model. Current regulations in part 438 do not explicitly address these entities as they were not a common model when the current regulations were drafted. Typically, a more robust PMPM fee has been paid to these entities, depending upon the scope of activities under the contract; however, these payments are not considered risk-based capitation payments subject to the actuarial soundness standards of § 438.4 through § 438.7 because the entities are not responsible for the provision of medical services under the state plan. Rather, the state continues to pay for medical services on a FFS basis. As these PMPM fees are not subject to the actuarial soundness standards, federal review and approval of these payments has been limited. In this rule, we propose to adopt a term for these more intensive care case management entities: PCCM entities. Our proposed term reflects our view that these entities are PCCMs subject to the statutory minimum standards for PCCMs but by distinguishing these entities from the traditional PCCM model—one based on the use of individual providers to act as gatekeepers—we can effectively exercise our authority under section 1902(a)(4) of the Act to adopt additional standards for those PCCM entities that provide more intensive case management and care coordination, measure performance outcomes and quality improvement activities, and receive higher reimbursement.

In at least seven states, PCCM entities provide many administrative functions of health plans—such as network management, data analysis, quality improvement support (including HEDIS measures and enrollee satisfaction surveys), utilization and case management of a whole range of services including behavioral health and LTSS. Finally, in a few instances, the state has built in shared savings or other incentive payment arrangements with the PCCM entity and that entity's participating providers which result in the PCCM entity realizing profits from its effective exercise of its functions. In essence, the only difference between an MCO and PCCM entity in these states is that the PCCM entity does not accept financial risk for acute care or LTSS services. However, if the entity receives shared savings or other payments as a result of decreasing costs for those services through the provision of primary care case management services, the entity shares the same financial incentives as managed care plans.

In 2009, the Center for Health Care Strategies, Inc., produced a report analyzing what they termed 'enhanced' PCCM programs in five states: North Carolina, Pennsylvania, Oklahoma, Indiana and Arkansas.[17] Since that time, both Colorado and Louisiana have implemented enhanced PCCM programs. These programs focus on intensive care management strategies coupled with financial incentives, provider profiling, and performance and quality reporting.

The benefit to these arrangements is that the state is able to receive FFP for payments to the PCCM entities, because primary care case management services are a state plan covered service under section 1905(a)(25) of the Act, rather than the 50 percent administrative match they would receive if the state conducted these case management activities, network management, data analysis, and quality improvement support (including HEDIS measures and enrollee satisfaction surveys) themselves. However, these activities are significantly more involved than those PCCM services described in the current regulatory definition of a PCCM: ''locating, coordinating and monitoring primary care services.'' Consistent with our goal of modernization, we propose to update our regulatory structure to recognize these expanded set of services, but couple that modernization with new standards on PCCM entities that have the same operational responsibilities and financial incentives as managed care plans—absent the financial risk for medical services.

We propose to also distinguish the PCCM programs that are considered managed care, and therefore, subject to the specified standards of part 438, from other health care delivery systems, such as integrated care models, patient-centered medical homes, and accountable care organizations which would remain outside the purview of the regulatory changes we are proposing in this rule. State Medicaid Director Letters (SMDL) issued in 2012 outlined new flexibilities for states to implement integrated care models that fall on the spectrum between unmanaged FFS and full-risk managed care. SMDL #12–002 specifically highlighted that primary care case management is a state plan service, which does not necessarily have to be a managed care delivery system, available at *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD-12-002.pdf*.

Notwithstanding the guidance in those SMDLs, states continue to seek clarification on the attributes of a PCCM program that make it ''managed care'' and they perceive that there are additional burdens if the program is considered a managed care program. We clarify in this preamble that states may operate PCCM programs—under the rubric of integrated care models, accountable care organizations or other similar terms—without triggering the standards of part 438 (which include additional contractual obligations) as long as enrollees' freedom of choice is not constrained and any willing and

[17] *http://www.chcs.org/usr_doc/EPCCM_Full_Report.pdf.*

qualified provider can participate—that is, where traditional FFS rules for provider participation remain in place. For such programs that use FFS provider participation, only the statutory standards in section 1905(t) of the Act that apply to PCCM contracts will apply, and not our further interpretations and applications of the provisions of section 1932 of the Act. We request comment on this proposal and our underlying analysis; further, we request comment on whether we should consider further rule-making to better explain these differences.

The framework we are using to modernize the managed care standards for PCCM programs (consistent with the discussion above) distinguishes between PCCM programs that utilize individual provider approaches to provide a basic level of primary care case management and PCCM programs that are using entities to provide a more robust set of administrative functions similar to that of a managed care plan. To clarify these distinctions, we propose in § 438.2 to exercise our flexibility under section 1902(a)(4) of the Act—to ensure proper and efficient management of the state plan—to update definitions for primary care case management and primary care case manager. We propose to modify the existing definition in § 438.2 for a ''primary care case management system'' as a system under which a state contracts either with an individual (primary care case manager) to provide case management services or when a state contracts with an entity to furnish case management services or a defined set of functions that go beyond case management services. We also propose to remove the reference to an ''entity'' under the existing definition of ''primary care case manager'' as an ''entity'' that provides primary care case management services is defined in the proposed new definition of ''PCCM entity'' that would permit a broader scope of functions to be provided than those focused on primary care case management services; these include such activities as intensive case management, development of enrollee care plans, execution of contracts and/or oversight responsibilities for the activities of FFS providers, provision of payments to FFS providers, enrollee outreach and education, operation of a customer service call center, provider profiling and quality improvement and measurement, coordination with behavioral health providers, and coordination with LTSS providers. We believe these functions are inclusive of the range of functions that current PCCM programs cover.

Throughout this document and in the revisions to part 438, we have included a reference to a PCCM entity wherever there was an existing standard on PCCMs. We have also identified those standards that only apply to PCCM entities when they undertake certain responsibilities on behalf of the state.

Existing law at § 438.6(k) (which we propose above to move to § 438.3(q)) implements the statutory provisions in section 1905(t) of the Act for PCCM contracts, which does not include a standard for our review and approval of those contracts. While we encourage states to submit them to us to assess compliance with the contract standards in this paragraph, most states do not do so. However, based on the range of functions that PCCM entities, as we have defined them, can provide to states as noted above, we believe that contract review and approval—similar to that of PIHPs and PAHPs under our authority under section 1902(a)(4) of the Act—is appropriate in this context. We believe our review would improve oversight and understanding of these programs. Therefore, we propose a new § 438.3(r) to have states obtain our approval of PCCM entity contracts. This proposed paragraph also specifies new standards that we propose elsewhere in this rule. For PCCM entities that have the same administrative responsibilities and financial incentives as MCOs, PIHPs, and PAHPs, states which hold their PCCM entities accountable for provider behavior and quality outcomes would have to monitor and evaluate the performance of their networks accordingly. Specifically, those PCCM entity contracts which provide for shared savings or other payment incentives—the same financial incentives that managed care plans have—should be held to higher standards in terms of enrollee information and quality improvement.

This proposed approach is consistent with the guidance that CMS has provided for integrated care models in SMDL #13–005 and SHO #13–007, available at *http://www.medicaid.gov/Federal-Policy-Guidance/Downloads/SMD-13-005.pdf* and *http://medicaid.gov/Federal-Policy-Guidance/Downloads/SHO-13-007.pdf*. The SMDL and SHO letter expressed our interest in achieving improved health, quality care and reduced costs. We noted that quality improvement and measurement are the foundation for payment models that can improve care and reduce costs, and encouraged states to develop statewide quality strategies that can guide efforts to improve quality across state Medicaid programs. Further, we laid out our expectations that states pursuing models that rely on measurable improvements as the basis for validation of payment, be able to articulate a comprehensive quality strategy that describes their overall goals and interventions. The difference in regulatory authority between integrated care models operating under the state plan and PCCM entities operating as a managed care entity should not result in differential treatment or expectations when the activities and responsibilities under an integrated care model and a PCCM entity are similar.

We have proposed changes to the following sections to effectuate these new standards related to PCCM entities that are also discussed in proposed § 438.3(r) at section I.B.2. of this proposed rule: § 438.10; § 438.330; § 438.340; and § 438.350. However, we do not propose to subject traditional PCCMs to these standards because PCCMs are not responsible for the activities that PCCM entities are responsible for under our proposed framework. In § 438.10, we propose to treat PCCM entities like MCOs, PIHPs and PAHPs in areas including oral and written translation standards; general and miscellaneous enrollee information standards; and enrollee handbook and provider directory content standards. In § 438.330, § 438.340 and § 438.350, we propose small modifications in each section, as follows, to propose new standards for PCCM entities:

- In § 438.330, we propose that states assess the performance of each PCCM entity to detect over- and underutilization of services; performance measurement using standard measures; and conduct a program review.
- In § 438.340, we propose that the state's quality strategy, consistent with the guidance provided in SMDL #13–007, describe how the state is assessing the performance and quality outcomes achieved by each PCCM entity.
- In § 438.350, we propose—based on inquiries received by states with PCCM entities—that the state may have their EQRO perform an external quality review of each PCCM entity. Since EQRs of MCOs, PIHPs, and PAHPs focus on the operation of the managed care plan, we believe that applying similar review principles to PCCM entities is reasonable and appropriate.

f. Choice of MCOs, PIHPs, PAHPs, PCCMs, and PCCM Entities (§ 438.52)

One of the key principles in federal statute and regulations is that enrollees—to the maximum extent possible—have a choice of more than one managed care plan. Section 1932(a)(3) of the Act requires that

choice be an element of a mandatory managed care program for MCOs and PCCMs and we adopted, in the 2002 final rule at current § 438.52, an application of that standard for PIHPs and PAHPs. By statute, enrollees in a mandatory managed care program must be given the choice of at least two ''managed care entities,'' a term defined as PCCMs and MCOs.

We are proposing modifications to § 438.52(a) to clarify current standards regarding the choice of two entities. Under the current regulation, states must give enrollees a choice of two MCOs, PIHPs, PAHPs, or PCCMs if enrollment with such an entity is necessary. In paragraph (a)(1), we propose to remove the reference to PCCM and provide that states that enroll beneficiaries in an MCO, PIHP or PAHP must give those beneficiaries a choice of at least two MCOs, PIHPs or PAHPs. As background, elsewhere in this proposed rule, we propose to separate PCCMs that are an individual physician (or physician assistant or certified nurse mid-wife) or a physician group practice from an entity or organization that employs such health care professionals and performs services on the state's behalf in addition to basic primary case management services. That proposal underlies the proposed amendments here for how the statutory choice standards would be implemented for PCCMs and PCCM entities. In paragraph (a)(2), we propose that in a primary care case management system, as currently defined in § 438.2, beneficiaries must be permitted to choose from at least two primary care case managers (PCCMs) employed by or contracted with the state. In paragraph (a)(3) we propose that beneficiaries who must enroll in a PCCM entity may be limited to one PCCM entity, but beneficiaries must be permitted to choose from at least two primary care case managers employed by or contracted with the PCCM entity. When a state's primary care case management system uses individual providers (physicians, physician assistants, etc.), for the provision of primary care case management services, beneficiary choice is exercised at that level. We recognize that for programs which use PCCM entities, virtually all states employ either regional organizations that serve every enrollee residing in that region or a single statewide organization. We believe that the statutory standard for choice is satisfied when a beneficiary is provided a choice of actual manager, namely that a beneficiary has the right under section 1932(a)(3) of the Act to select either a care manager/care coordinator employed by the entity or a primary care provider contracted with the entity (or in some cases, by the state directly). Our proposed changes explicitly permit such an approach.

In addition, section 1932(a)(3)(B) of the Act provided an exception to the standard that an enrollee have the choice of at least two MCOs, or PCCMs, if applicable, for states with rural areas. This exception is reflected in the current regulations at § 438.52(b), wherein the exception to choice was extended to PIHPs and PAHPs. We propose two significant changes to the implementation of the rural area exception. First, as a consequence of our proposal to change the implementation of the enrollee choice standards, we propose to eliminate the rural exception for PCCMs.

Second, we propose to change the definition of a rural area for purposes of the state option to contract with one MCO, PIHP, PAHP, or PCCM under mandatory Medicaid managed care programs. The current definition of a rural area at § 438.52(b)(3) is any area other than an ''urban'' area as specified in the Office of Management and Budget's (OMB) delineation of Metropolitan Statistical Areas (hereinafter OMB Bulletin). The OMB Bulletin produces geographic distinctions focused on a core population center that has a high degree of social and economic integration with adjacent territories as measured by commuting ties, which can include less densely populated areas within a Metropolitan Statistical Area (MSA). OMB has consistently warned against the non-statistical use of the delineations within the OMB Bulletin, noting that: ''Metropolitan and Micropolitan Statistical Area Standards do not produce an urban-rural classification, and confusion of these concepts can lead to difficulties in program implementation [for programs that rely on such distinctions].'' *See* for example 75 FR 37236 (June 28, 2010).

Our experience working with states that have sought to exercise the rural exception to choice gives credence to OMB's statement. We have encountered a number of states seeking to contract with one MCO, PIHP, PAHP, or PCCM system in sparsely populated counties that are classified as part of an MSA and cannot meet the current regulatory definition for a rural area. We believe the intent of the provision was to recognize the health care access challenges unique to rural areas as well as the likelihood that MCOs, PIHPs, and PAHPs could not sustain their financial model in areas with low Medicaid enrollment.

To better reflect the intent of the provision, we propose to adopt Medicare's county-based classifications to set network adequacy standards under the MA program. Medicare establishes population and density parameters based on approaches taken by the Census Bureau in defining ''urbanized areas'' and OMB's delineation of ''metropolitan'' and ''micropolitan'' areas. These parameters are then used to set nationwide county designations as ''large metro,'' ''metro,'' ''micro,'' ''rural,'' or ''Counties with Extreme Access Considerations (CEAC).'' The county designations are published annually in the MA Health Services Delivery (HSD) Reference file, which is accessible at the MA Applications page at *http://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/index.html?redirect=/MedicareAdvantageApps/*. We propose that a county with a designation other than large metro or metro would fall under the definition of a rural area for purposes of the rural exception to choice. We believe that the Medicare county designations would be easy for states to research and for us to confirm a county's classification as rural. In addition, we believe that a number of states that were barred from exercising the rural exception to choice under the existing standard would see greater flexibility with the proposed change. We believe that the modification to the definition of a ''rural'' area for purposes of exercising the exception to choice of health plans addresses past challenges faced by some states. However, consistent with the key principle in favor of plan choice outlined earlier, we continue to encourage the provision of such choice to beneficiaries where feasible.

We considered adopting the geographic distinctions used by the Office of Rural Health Policy (ORHP) within the Health Resources and Services Administration (HRSA) for purposes of determining a provider's eligibility for grant funding available through that agency. ORHP's definition of a rural area identifies lower population counties or census tracts within a county that otherwise fall under OMB's delineation of MSAs. Census tracts are defined at the zip code rather than county level, so it is possible for a county to include multiple census tracts of different population densities. If we were to adopt ORHP's approach, we would need to establish a review standard for a county that as a whole did not qualify as rural and states would have the burden of researching the

nature and scope of the census tracts to meet the standard.

g. Non-Emergency Medicaid Transportation PAHPs (§ 438.9)

As states' managed care programs have matured, states have used PAHPs for a broader scope of services than was initially considered when the Medicaid managed care rules were finalized in 2002. With that in consideration, we propose additional provisions throughout part 438 to address PAHPs providing medical services (as currently defined in § 438.2) which are discussed throughout the preamble of this proposed rule. However, we understand that states may also use a PAHP structure to deliver only Non-Emergency Medical Transportation (NEMT) services when they are not using the state plan brokerage option authorized through section 1902 of the Act or providing NEMT through Medicaid FFS or as an administrative activity. We do not believe that states and PAHPs providing only NEMT services should have to comply with the full scope of PAHP provisions included in part 438. Therefore, we propose to amend the existing § 438.8 to include only the specific provisions applicable to NEMT PAHPs.

First, we propose to change the section number of § 438.8 to § 438.9 because of additional sections added to the beginning of the subpart. Second, in an effort to avoid duplicative information, we propose to delete the existing language in paragraphs (a) and (b) as all the PIHP and PAHP provisions listed in the existing paragraphs are specified throughout the regulatory text of part 438 and, therefore, it is unnecessary to include a separate section listing the standards applicable to PIHPs and PAHPs. We propose a new paragraph (a) which defines an NEMT PAHP as an entity that provides only NEMT services to enrollees under contract with the state on a pre-paid capitated basis or other payment arrangement that do not use state plan payment rates. If a state chooses to use a PAHP to provide NEMT services along with any other ambulatory medical service, that PAHP would then be considered a traditional PAHP as defined in § 438.2 and all the PAHP provisions throughout part 438 would apply. Lastly, in paragraph (b) we list the specific provisions in part 438 that would apply to NEMT PAHPs in the same way they apply to any other PAHP. The provisions that apply include contracting provisions, actuarial soundness standards, information standards, anti-discrimination provisions, certain state responsibility provisions, certain enrollee rights and responsibilities, certain PAHP standards, right to fair hearings, and certain program integrity standards. We believe this list achieves the appropriate balance of beneficiary protections and administrative efficiency for States and NEMT PAHPs.

h. State Plan Standards (§ 438.50)

Section 438.50 governs state plan standards for programs with mandatory managed care enrollment and currently has a reference to ''managed care entities.'' Although defined in the statute, ''managed care entities'' is an undefined term in the regulation. Because this provision only applies to MCOs and PCCMs as referenced later in § 438.50, we propose to replace the term ''managed care entities'' with ''MCOs, PCCMs, or PCCM entities, as applicable.''

In addition, we propose to delete paragraphs (e) and (f), which addressed priority and default enrollments for managed care programs operated under section 1932(a) of the Act. These processes, along with other general standards for enrollment, that are applicable to all authorities for managed care programs are provided in the proposed new § 438.54.

7. Implementing Statutory Provisions

a. Encounter Data and Health Information Systems (§ 438.2, § 438.242 and § 438.818)

Sections 6402(c)(3) and 6504(b)(1) of the Affordable Care Act reorganize, amend, and add to the provisions of sections 1903(i)(25) and 1903(m)(2)(A)(xi) of the Act by adding provisions related to routine reporting of encounter data as a condition for receiving federal matching payments for medical assistance. Section 1903(i)(25) of the Act mandates that, effective March 23, 2010, federal matching payments to the states must not be made for individuals for whom the state does not report enrollee encounter data to us. Further, section 1903(m)(2)(A)(xi) of the Act specifies that an MCO must report ''patient encounter data'' for contract years after January 1, 2010, to the state in a timeframe and level of detail specified by the Secretary. As discussed below, the data that must be collected and reported under these provisions is the same, but the population of ''enrollees,'' compared to ''patients,'' includes enrollees of PIHPs and PAHPs under our interpretation.

Since effective monitoring of all programs from which enrollees receive services is a critical function, we are proposing to expand the contract standards that apply the provisions of section 1903(m)(2)(A)(xi) of the Act to PIHPs and PAHPs by utilizing authority under section 1902(a)(4) of the Act to ensure the proper and efficient operation of the State plan.

In issuing these provisions, we propose to add the following:

- A definition of enrollee encounter data in § 438.2;
- Additional MCO, PIHP, and PAHP contract standards defining enrollee encounter data submission and maintenance standards;
- Clarifications to better align the basic elements of a health information system with the Affordable Care Act; and
- Standards on the state to report accurate, complete, and timely enrollee encounter data to us as a condition for receiving federal matching payments on its MCO, PIHP, and PAHP contract expenditures.

In § 438.2, we propose to define enrollee encounter data as the information relating to the receipt of any item(s) or service(s) by an enrollee under a contract between a state and a MCO, PIHP, or PAHP that is subject to the standards of §§ 438.242 and 438.818.

We propose to revise § 438.242 to clarify and align the basic elements of a MCO, PIHP, or PAHP health information system with the Affordable Care Act. The size and scope of today's Medicaid programs need robust, timely, and accurate data to ensure the highest financial and program performance, support policy analyses, and maintain ongoing improvement that enables data-driven decision making. In August 2013, we released SMDL #13–004 that issued guidance to states on the Transformed Medicaid Statistical Information System (T–MSIS) *http://www.medicaid.gov/Federal-Policy-Guidance/Downloads/SMD-13-004.pdf*. We intend to review whether managed care entities provide timely and accurate encounter data to facilitate the transition to T–MSIS. Future guidance and revisions to the CMS EQR protocols would reflect this ongoing effort. In paragraph (a) we use authority in section 1902(a)(4) of the Act for the proper and efficient administration of the state plan and propose to include PAHPs as being subject to the standards. This is in alignment with the reasoning for expanding numerous other standards throughout this part to PAHPs; that is, the services they are contracted to provide are important and they must be held as fully accountable as MCOs and PIHPs and enrollees of PAHPs must be afforded the same protections as MCO and PIHP enrollees. Additionally, the reference to having sufficient data to

achieve the objectives of ''this subpart'' is changed to ''this part'' to emphasize the critical role data plays in achieving the objectives throughout part 438.

In § 438.242(b)(1), we propose a specific reference to the new standard in section 6504(a) of the Affordable Care Act, which would mandate that state claims processing and retrieval systems be able to submit data elements to us deemed necessary for Medicaid program integrity, oversight, and improvement. Existing paragraph (b)(1) is redesignated as paragraph (b)(2) and proposes to add ''all'' to clearly indicate that data collected by the State would have to include all services furnished to an enrollee. To further support our intent, in paragraph (b)(3)(i), we propose to add ''including capitated providers'' as this is currently a data weakness for many states, MCOs, PIHPs, and PAHPs. Utilization data from capitated providers is frequently less robust, or in some cases non-existent. This data is equally as important as the data from providers paid on a FFS basis and must be incorporated and utilized in all MCO, PIHP, and PAHP functions.

We propose a new § 438.242(c) to add enrollee encounter data standards that would have to be incorporated in all MCO, PIHP, and PAHP contracts. Contracts would have to specify that enrollee encounter data must: include rendering provider information; be submitted in a manner compliant with our specifications and in accordance with the standards of § 438.818; and be submitted to the State in a format consistent with the industry standard ASC X12N 835, ASC X12N 837, and NCPDP formatting. In paragraph (c)(2), we propose that MCOs, PIHPs, and PAHPs submit data at a level of detail to be specified by CMS. To retain flexibility to adapt to changes in payment practices over time, we anticipate issuing clarifying guidance in the future to provide specificity. At a minimum, we expect the initial guidance to include standards for MCOs, PIHPs, and PAHPs to submit to the state: enrollee and provider identifying information; service, procedure and diagnosis codes; allowed/paid, enrollee responsibility, and third party liability amounts; and service, claim submission, adjudication, and payment dates.

We propose to add a new § 438.818 entitled Enrollee Encounter Data to implement the standard for enrollee encounter data reporting by the state. In this section, we propose that federal matching payments would not be available for states that do not meet established data submission benchmarks for accuracy, completeness, and timeliness. Timeliness and frequency of reporting encounter data is a key issue in terms of alignment between the managed care delivery system and the FFS Medicaid delivery system. We released guidance in 2013 [18] that clarified the data elements, reporting structure for, and frequency of enrollee encounter data in the Medicaid Statistical Information System (MSIS). Those standards mandate monthly submission for all FFS and managed care data.

In addition to receipt of data in a timely manner, receipt of data that is accurate and complete is integral to our administration and oversight of state Medicaid programs. This means that encounter data submitted to us must represent all services received by an enrollee regardless of payment methodology, including services sub-capitated by a MCO, PIHP, or PAHP to a provider. In proposed § 438.818(a), we restate the statutory provision prohibiting FFP unless the state meets the standards for submitting encounter data. Proposed paragraph (a)(1) would have the submission of encounter data be compliant with current HIPAA security and privacy standards and in the format needed by the Medicaid Statistical Information System (MSIS) or any successor format. MSIS and T–MSIS are the repositories of all encounter data for the Medicaid program and although submission of data to MSIS has been a standard for years, states have not always invested the resources needed to ensure the quality of the submissions. We propose these changes to support efforts currently underway to improve the accuracy, timeliness, and completeness of submissions. In proposed paragraph (a)(2), the state would have to validate enrollee encounter data before each submission to us. States may use various methods to ensure the accuracy and completeness of the encounter data. One such method may be to use the protocol defining the optional External Quality Review (EQR) activity for Encounter Data Validation. States that use their EQRO to conduct Encounter Data Validation can receive 75 percent match for those contract expenses as specified in section 1903(a)(3)(C)(ii) of the Act. We expect that if a State chooses a different method, it will ensure that there is sufficient analytic rigor in the chosen method. We request comment on other possible methods for achieving validated data in each submission.

Proposed § 438.818(a)(3) would reinforce the importance of complying with all MSIS encounter data reporting standards as a condition for receipt of FFP. Encounter data is just one piece of a complete MSIS submission. To maximize our ability to fully integrate and utilize all MSIS data for comprehensive analysis and oversight, encounter data needs to be fully compliant. In § 438.818(b) and (c), we propose to review each encounter data submission for accuracy and potentially defer or disallow payment to a state if it is determined that the enrollee encounter data set is not complete, accurate, and timely. If, after review of an encounter data submission, we determine that it does not comply with established criteria, we propose to provide the State with a reasonable opportunity to make the submission compliant. If the State is unable to make the submission compliant within the time allowed, we propose to defer and/or disallow FFP for the MCO, PIHP, or PAHP contract in question. We believe that the statute contemplates a per-enrollee disallowance for a failure to report enrollee encounter data. We believe it is more accurate to calculate the deferral and/or disallowance amount based on the enrollee and the specific service type of the non-compliant data. Using this methodology, only the portion of the capitation payment attributable to that enrollee for the service type of the non-compliant data would be considered for deferral and/or disallowance. For example, if the non-compliant encounter data is for inpatient hospital services, then only the inpatient hospital portion of the capitation payment for that enrollee would be subject to deferral and/or disallowance.

Any reduction in FFP would be effectuated through the process outlined in § 430.40 and § 430.42.

In § 438.818(d), we are proposing that within 90 calendar days of the effective date of the final regulation, states would have to submit to us a detailed plan of their procedures to ensure that complete and accurate data are being submitted timely. We would work with the states to develop a comprehensive and workable procedure and would review and approve the states' plans for compliance.

b. Standards for Contracts Involving Indians, Indian Health Care Providers and Indian Managed Care Entities (§ 438.14)

This section implements section 5006(d) of the American Reinvestment and Recovery Act of 2009, which created section 1932(h) of the Act governing the treatment of Indians, Indian health care providers and Indian

[18] *http://www.medicaid.gov/Federal-Policy-Guidance/Downloads/SMD-13-004.pdf.*

managed care entities, participating in Medicaid managed care programs. We had previously provided guidance on this statutory provision in a State Medicaid Director Letter on January 22, 2010 (SMDL #10–001, ARRA #6) *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD10001.PDF.* The regulations proposed below implement that guidance consistent with statutory language. To ensure the proper and efficient operation of the state plan, we are proposing to expand the standards that apply the provisions of section 1932(h) of the Act to PIHPs and PAHPs through the authority under section 1902(a)(4) of the Act.

In this section and for this purpose, we propose in paragraph (a) to define the following terms: ''Indian,'' ''Indian health care provider (IHCP),'' and ''Indian managed care entity (IMCE)'' consistent with statutory and existing regulatory definitions.

In paragraph (b), we propose that each MCO, PIHP, PAHP, and PCCM entity's contract must demonstrate sufficient IHCPs in the managed care network and that Indian enrollees be able to obtain services from them; that IHCPs be paid for covered services provided to Indian enrollees who are eligible to receive services from such providers whether the IHCP participates in the managed care network or not; permit any Indian who is enrolled in a non-Indian managed care entity and eligible to receive services from a participating IHCP to choose that IHCP as his or her primary care provider, as long as that provider has capacity to provide the services; permit Indian enrollees to obtain covered services from out-of-network IHCPs; and in any state where timely access to covered services cannot be ensured due to few or no IHCPs, a MCO, PIHP or PAHP would be considered to have met the standard for adequacy of IHCP providers if either Indian enrollees are permitted to access out-of-state IHCPs, or the state deems the lack of IHCP providers to justify good cause for an Indian's disenrollment from both the MCO, PIHP or PAHP and the State's managed care program in accordance with § 438.56(c). We believe the criteria established in proposed paragraph (b)(5) complies with section 1932(h)(2)(A)(ii) of the Act which provides for the Secretary to establish procedures for determining compliance with this standard.

We invite comment on other possible ways to approach this issue.

Proposed § 438.14(c) outlines payment standards. Proposed paragraph (c)(1) specifies that when an IHCP is enrolled in Medicaid as a FQHC but is not a participating provider with a MCO, PIHP or PAHP, it must be paid FQHC payment rates, including any supplemental payment due from the state. Where the IHCPs is not enrolled in Medicaid as a FQHC, proposed paragraph (c)(2) would have the MCO, PIHP, or PAHP payment be the same payment as it would receive using a FFS payment methodology under the State plan or the applicable encounter rate published annually in the **Federal Register** by the Indian Health Service, regardless of its contracting status with the MCO, PIHP or PAHP.

Proposed paragraph (d) would implement the statutory provision permitting an IMCE to restrict its enrollment to Indians in the same manner as Indian Health Programs may restrict the delivery of services to Indians, without being in violation of the standards in § 438.3(d).

This proposed rule has tribal implications and is therefore, subject to the CMS Tribal Consultation Policy (November 2011) *http://www.cms.gov/Outreach-and-Education/American-Indian-Alaska-Native/AIAN/Downloads/CMSTCP_FINAL_11_17_11.pdf.* Consistent with this policy, we held an All Tribes' Call on May 7, 2014 and considered tribal comments received at that time. In addition, prior to publication of the final rule, we will conduct further tribal consultation. This consultation process is in addition to the notice and opportunity for comment otherwise provided in the rulemaking process. We provided a detailed review of the provisions proposed in § 438.14 as well as a brief overview of the entire scope of changes being made to the part. One participant provided feedback on two areas: the applicability of these provisions to PIHPs and PAHPs; and the applicability of the prompt payment provisions to the state for wrap payments. Our staff explained that the proposed regulations would apply to PIHPs and PAHPs to the same extent as they would apply to MCOs. We also clarified that the prompt payment provisions proposed in § 438.14(d) do not apply to payments made by the state; however, section 1902(bb)(5)(B) of the Act addresses prompt payment standards for states.

We seek comment on the overall approach to this provision, including as to whether these proposals are adequate to ensure that Indian enrollees have timely and integrated access to covered services consistent with section 5006 of the ARRA. We seek comment on how to facilitate a coordinated approach for care for Indian enrollees who receive services from a non-participating IHCP and who need Medicaid covered services through a referral to a specialty provider. Also, we seek comment on the potential barriers to contracting with managed care plans for IHCPs and what technical assistance and resources should be made available to states, managed care plans, and IHCPs to facilitate these relationships. Such resources might include an I/T/U contract addendum, similar to those created for the QHPs and organizations delivering the Medicare Part D benefit. *See https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Model_QHP_Addendum_Indian_Health_Care_Providers_04-25-14.pdf* and *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2014-Part-D-Application.pdf,* at Appendix XVII.

c. Emergency and Post-Stabilization Services (§ 438.114)

We propose to revise portions of § 438.114 to make technical corrections to the existing regulations. We are not proposing any changes to paragraph (a), (d), and (f).

We propose to correct an error in the current regulations at paragraph (b) by removing paragraph (2) which refers to PCCMs with a risk contract. This provision is inconsistent with the rest of our managed care regulatory structure, in that a PCCM which accepts risk for medical services—including the emergency services referenced in this section—would be considered either a PAHP or PIHP (depending on the scope of medical services at risk). Because a PCCM would never be responsible for coverage and payment of emergency services, we have struck that reference from paragraph (b). A state will always be responsible for coverage and payment of emergency services if it operates a PCCM program, which is reflected in the proposed revisions to paragraph (b)(2), where we propose to move the existing text in (b)(3) with the addition of ''PCCM entities.''

In paragraph (c)(1), we propose to add PCCM entity to each reference to ''MCO, PIHP, PAHP, or PCCM'' for consistency with changes discussed in I.B.6.e of this proposed rule. In paragraph (c)(2), we propose to redesignate (c)(2)(i) as (c)(2) and delete (c)(2)(ii) for the reason described previously for paragraph (b).

Currently in paragraph (e), MCOs, PIHPs, and PAHPs must follow MA guidelines when covering post-stabilization services and be paid in accordance with Medicare guidelines. However, payment for post-stabilization services to Medicaid enrollees is governed by Medicaid and State rules.

We correct this misleading provision by proposing language that ensures that hospitals providing post-stabilization services receive payment consistent with federal and State Medicaid payment standards, not based on Medicare rates. The resulting language would apply MA coverage guidelines to MCOs, PIHPs and PAHPs but Medicaid payment standards for covered post-stabilization services.

8. Definitions and Technical Corrections

a. Definitions

As discussed throughout this proposed rule, we propose to redesignate and add several definitions to § 438.2 in connection with changes we have proposed to specific sections and subparts. In addition, we are proposing several modifications and additions to § 438.2 to address terms used throughout this part. In § 438.2 we propose to modify existing definitions for ''capitation payment,'' ''comprehensive risk contract,'' ''health care professional,'' ''health insuring organization,'' ''managed care organization,'' ''nonrisk contract,'' ''prepaid ambulatory health plan,'' ''prepaid inpatient health plan,'' and ''risk contract.'' In addition, we propose to add definitions for ''managed care program,'' ''network provider,'' and ''state,'' which are terms used with some frequency in part 438 but are not currently defined.

For the existing definition of ''capitation payment,'' we propose to delete the word ''agency'' following ''state,'' consistent with our proposal to add a definition for ''state.'' In addition, we propose to remove the word ''medical'' that modifies ''services'' in recognition of our proposed changes throughout this proposed rule to incorporate managed long-term services and supports in part 438.

For the existing definition of a ''comprehensive risk contract'' we propose to add that the contract is ''between the State and an MCO.'' We believe that this proposed modification would make clear that only MCOs can have comprehensive risk contracts and it is also appropriate to identify the parties to the contract.

We propose to revise the definition for ''health care professional.'' For purposes of section 1932(b)(3)(C) of the Act, ''health care professional'' is defined as a ''physician . . . or other health care professional if coverage for the professional's services is provided under the contract'' and sets forth a minimum list of health care professionals that may provide services covered under the managed care contract. We propose to include language from the statutory definition in the regulation that the physician's or provider's services are covered under the contract in our regulatory definition of ''health care professional'' to clarify that providers of services other than medical services, such as long-term services and supports, would be included in this definition. We also propose to delete the list of professionals in section 1932(b)(3)(C) of the Act from our regulatory definition of ''health care professional'' because the list was not intended to be exclusive and inclusion of this list in the regulatory definition does not clarify our intent for this definition. We request comment on this approach.

In the existing definition of a ''health insuring organization,'' we propose to correct a technical error to the citation to the Omnibus Budget Reconciliation Act of 1985 and update the reference to statutes that have since amended the HIO-related provisions established in the 1985 statute.

In the existing definition of a ''managed care organization'' we propose to clarify, consistent with section 1903(m) of the Act that the Secretary determines if the conditions specified are met by an entity seeking to qualify for a comprehensive risk contract. The existing language does not identify who makes such a determination.

In the proposed definition of a ''nonrisk contract,'' we propose language to clarify that such a contract is between the state and a PIHP or PAHP. This proposed revision is consistent with the proposed change to identify the parties subject to a ''comprehensive risk contract.'' Consistent with the revisions proposed for ''capitation payments,'' we propose to remove ''medical'' as the modifier for ''services'' in the definitions for ''prepaid ambulatory health plan'' and ''prepaid inpatient health plan.'' We also propose to remove ''agency'' that follows ''state'' consistent with our proposal to add a definition for ''state.''

In the existing definition of a ''risk contract,'' we propose to clarify that such a contract is between the state and MCO, PIHP or PAHP. This proposed revision is consistent with the proposed change to identify the parties subject to a ''comprehensive risk contract.''

We propose to add a definition for the phrase ''managed care program,'' which is currently used in several sections of this part. We propose this term mean a managed care delivery system operated by a state as authorized in the 1915(a) or (b), 1932(a), or 1115(a) of the Act.

We propose to add a definition for ''network provider,'' a term that is currently used in several sections of this part, as ''a health care professional, group of health care professionals, or entity that receives Medicaid funding directly or indirectly to order, refer, or render covered services as the result of the state's arrangement with an MCO, PIHP, or PAHP.'' We intend this term to include all types of health care professionals, either as an individual or through a group, and entities that order, refer, or render covered Medicaid services. We believe that these distinctions recognize the arrangements in some state where MCOs, PIHPs, or PAHPs contract with provider groups or other MCOs, PIHPs, or PAHPs to carry out the obligations under the contract. We also propose to insert ''network provider'' in place of ''affiliated provider'' as used in this part for consistency in use of terminology.

We currently have inconsistent references to the ''state,'' ''state Medicaid agency'' or ''agency'' throughout part 438. Therefore, we propose to add a definition for ''state'' as the ''Single State Agency'' as defined in § 431.10. We also propose to replace the aforementioned terms with ''state'' for consistency throughout part 438.

b. Technical Corrections

We propose to correct a limited number of technical and typographical errors identified in the June 14, 2002 final rule and the October 25, 2002 correcting amendment, as well as those identified through our review of the existing regulations in part 438.

- We propose to update the cross-reference to cost-sharing rules in § 438.108 to reflect recent revisions to part 447.
- For purposes of consistency throughout part 438, we are removing specific references to our Regional Office in § 438.806(a)(1) and replacing it with a general reference to CMS. This proposed change does not represent a modification in the role of the Regional Offices; rather, we would prefer to establish workflow processes in sub-regulatory guidance rather than in regulation.
- We propose to delete § 438.804 related the primary care provider payment increase under section 1202 of the Affordable Care Act as that provision expired at the close of calendar year 2014.

II. CHIP Requirements

A. Background

CHIPRA and the Affordable Care Act applied several Medicaid managed care

provisions in section 1932 of the Act to CHIP. Specific Medicaid statutory provisions that apply to CHIP include: section 1932(a)(4), Process for Enrollment and Termination and Change of Enrollment; section 1932(a)(5), Provision of Information; section 1932(b), Beneficiary Protections; 1932(c), Quality Assurance Standards; section 1932(d), Protections Against Fraud and Abuse; section 1932(e), Sanctions for Noncompliance; and sections 1902(a)(77) and 1902(kk) of the Act related to provider and supplier screening, oversight, and reporting.

This proposed rule builds on initial guidance on the implementation of section 403 of CHIPRA provided in State Health Official (SHO) letters 09–008 and 09–013, issued on August 31, 2009 and October 21, 2009, respectively. (SHO #09–008 is available at: *http://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SHO083109a.pdf*. SHO #09–013 is available at *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SHO102109.pdf*.) The SHO letters specified that all CHIP managed care contracts were to include the provisions of section 2103(f) of the Act, as amended by section 403 of CHIPRA effective July 1, 2009. Because the provisions addressed in this proposed rule codify statute and guidance that has been in place since 2009, we anticipate that states have already implemented many of these provisions as outlined in the SHOs.

Our goal for these regulations is to align CHIP managed care standards with those of the Marketplace and Medicaid where practical. This will ensure consistency across programs. In this same rule, we propose revisions to existing Medicaid regulations as part of an effort to modernize managed care contracting and service delivery while improving health care outcomes and beneficiary experience in a cost effective manner. Therefore, where appropriate, we propose to align the CHIP managed care regulations with some of the proposed revisions to the Medicaid managed care rules.

We recognize that CHIP has historically had few regulations related to managed care. Our intent with this proposed rule is to ensure transparency by increasing the information about CHIP managed care available to both the Federal government and the public. We have worked to balance the need for information about state oversight of CHIP managed care plans against the administrative burden of complying with the proposed regulations. To that end, we propose to only apply the rules that are most important for aligning CHIP managed care with Marketplace and Medicaid managed care rules. The scope of the CHIP proposed regulations is narrower than the proposed revisions and amendments to the Medicaid managed care regulations. Most of the proposed CHIP regulatory changes are limited in scope to those included in section 403 of CHIPRA and, where allowable, those changes that will align the program with the Marketplace. We seek comment on the breadth of the proposed CHIP managed care regulations compared to the proposed Medicaid managed care regulations and whether CHIP should incorporate additional standards from Medicaid.

B. Provisions of the Proposed Regulations

We propose adding a new subpart L to part 457, which will contain all of the regulations related to CHIP managed care plans. Most of the proposed regulations in this subpart are new, however we also propose to move portions of § 457.940 and § 457.950 and all of § 457.955 from subpart I to the new subpart. This will ensure that all information related to managed care is contained in one subpart. We propose to make revisions to § 457.204 related to federal financial participation. In addition, we propose to revise § 457.760 related to Strategic Planning, Reporting, and Evaluation.

1. Definitions (§ 457.10, § 457.902)

We propose to update the definitions section at § 457.10. First, we propose to separately define managed care organization (MCO), prepaid ambulatory health plan (PAHP), prepaid inpatient health plan (PIHP), primary care case management primary care case manager (PCCM), and PCCM entity, using the Medicaid definitions at § 438.2. This is a change from our previous approach which included all types of managed care entities in a single term (managed care entity). We also propose to adopt the Medicaid definitions of comprehensive risk contract, external quality review (EQR), external quality review organization (EQRO), and risk contract. Finally, we propose to move, unchanged, the definition of actuarially sound principles and FFS entity to § 457.10 from § 457.902.

2. Federal Financial Participation (§ 457.204)

We are not adopting Medicaid managed care regulations related to withholding Federal financial participation for failure to comply with Federal regulations in subpart J of part 438, because we believe CHIP has an existing regulation (§ 457.204) that serves a similar purpose. We propose to clarify in § 457.204(a) that CMS may withhold federal financial participation if the administrator finds that the state plan or state practice is in substantial non-compliance with the regulations in part 457. In addition, we propose to include examples of substantial non-compliance, including failure to comply with requirements that significantly affect federal or state oversight or state reporting. We do not intend the list of examples in § 457.204 to be comprehensive; we leave open the possibility that other actions or failures to act could amount to substantial non-compliance with title XXI of the Act or the regulations in part 457.

3. Basis, Scope, and Applicability (§ 457.1200)

In § 457.1200, we describe the statutory basis and scope of proposed subpart L. We propose to primarily limit the scope of the CHIP regulations to those included in section 2103(f)(3) of the Act, as added by section 403 of CHIPRA. That section applies sections 1932(a)(4), 1932(a)(5), 1932(b), 1932(c), 1932(d), and 1932(e) of the Act to CHIP. In addition, we propose to implement section 2107(e)(1)(M) of the Act, as added by section 5006 of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5, ARRA). This provision applies sections 1932(a)(2)(C) and 1932(h) of the Act, which provide protections for American Indians to CHIP. We also propose to implement statutory provisions related to program integrity, specifically sections 2107(b) and 2107(e)(2)(C) through (E) of the Act. Finally, we also rely on section 2101(a) of the Act, which provides that the purpose of Title XXI is to provide funds to states to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner. We seek comment on whether this approach is appropriate, or whether we should narrow or broaden the CHIP regulations.

4. Contracting Requirements (§ 457.950, § 457.1201)

Previously, all CHIP contracting requirements, including managed care contracting requirements, were at § 457.950. We propose to move some pieces of § 457.950 related to managed care into a new § 457.1201 and eliminate others. Specifically, we have retained from § 457.950(a)(2) the provision that an MCO, PAHP, or PIHP (formerly referred to as MCEs) contract include an attestation to the accuracy, completeness, and truthfulness of claims and payment data at

§ 457.1201(n). Similarly, at § 457.1201(o), we retain the language from § 457.950(a)(4) that contracts include a guarantee that an MCO, PAHP, or PIHP (formerly MCE) will not avoid costs for services covered in its contract by referring enrollees to publicly supported health care resources. We propose to eliminate the requirements at § 457.950(a)(1) and § 457.950(a)(3) for contracts to include enrollment and other information, and for the state, CMS, and HHS Office of the Inspector General to have access to claims and payment data. We believe these requirements are subsumed in the other standards in § 457.1201, described below, and do not need to be retained, however we seek comment on this approach.

We also propose new contracting standards in § 457.1201, under the authority of section 2101(a) of the Act. Although we previously did not require submission of managed care contracts, there were also few statutory managed care requirements. Now that the CHIP statute has been amended to incorporate some of the Medicaid managed care requirements, it is more important for CMS to have oversight through contract review. We propose some CHIP-specific contracting requirements and propose to adopt some of the Medicaid standards from § 438.3. The Medicaid standards we have adopted without modification relate to the relevant entities eligible for comprehensive risk contracts, the inclusion of payment rates, some of the prohibitions on enrollment discrimination, complying with applicable laws and conflict of interest safeguards, the inspection and audit of records and access to facilities, physician incentive plans, provider choice, audited financial reports, and some of the additional rules for contracts with PCCMs and PCCM entities.

Our proposed CHIP-specific provisions at § 457.1201(a) would have states submit CHIP managed care contracts in accordance with standards that will be specified by the Secretary. We do not propose to condition FFP on CMS' prior approval of MCO contracts, which diverges from the Medicaid standards at § 438.3 and § 438.806. We considered two alternative policies: aligning CHIP with the Medicaid standard that prior approval of the contract is a condition to receive FFP; or requiring submission of the contract to receive FFP. Because we do not currently require contract review and preapproval as a condition for FFP in CHIP managed care, we have proposed an approach that would begin to give CMS and the public information on CHIP managed care contracting. Once we have learned more, we may consider adopting additional standards. We seek comment on our proposed approach and the alternatives, and on the timing of submission of contracts.

Similarly, although we are not adopting Medicaid rules related to rate review, the proposed language at § 457.1201(a) does require that CHIP contracts submitted to CMS include the rate that will be paid to the managed care entity. We believe this information will help us evaluate the cost, efficiency, and effectiveness of managed care contracts.

There are several standards at § 438.3 that we do not propose to adopt in CHIP, either because we do not have authority or because they are not appropriate for the CHIP population. Specifically, we are not proposing to adopt the following standards for purposes of CHIP managed care plans:

- That health insurance organizations (HIO) described in § 438.3(b)(4) and (b)(5) are eligible for comprehensive risk contracts, and the special rules related to HIOs in § 438.3(p) because CHIP does not have such entities.
- Voluntary enrollment at § 438.3(d)(2), because states may have exclusively mandatory enrollment in CHIP managed care;
- The list of services that may be provided by a managed care entity at § 438.3(e) because we review rates in CHIP;
- The provider preventable condition standards at § 438.3(g), because we do not require such reporting in CHIP;
- The advance directives standard at § 438.3(j) or LTSS contract standards at § 438.3(o) because we do not believe they are applicable to the CHIP population;
- The standards related to coverage of outpatient drugs at § 438.3(s); and
- The standards related to dually eligible beneficiaries at § 438.3(t) and enrollees that are patients in an IMD at § 438.3(u), because there are not applicable populations in CHIP.

5. Rate Development Standards and Medical Loss Ratio (§ 457.940, § 457.1203, § 457.1205)

Currently, regulations related to CHIP managed care rate setting are in § 457.940(b)(2), (c), and (e). We propose to move those standards to § 457.1203. The standards would remain substantively unchanged, although we propose to change the term ''principles of actuarial soundness'' to ''actuarially sound principles,'' to match the definition, which we propose to move to § 457.10. The standards unrelated to managed care rate setting in § 457.940(a), (b)(1), and (d) would remain in that section. In addition, to align with the private market and the Medicaid managed care proposal in this rule, we propose at § 457.1203(c) to adopt a minimum medical loss ratio (MLR) in CHIP. This proposal is the same as the Medicaid proposal at § 438.4(b)(7). As discussed in more detail elsewhere in this proposed rule, a standardized MLR calculation allows regulators the ability to conduct a retrospective analysis of rates paid compared to overall expenditures to ensure a fair and equitable arrangement is maintained and is a useful means to ensure that capitation rates are actuarially sound. Both reasons are applicable to CHIP managed care plans because of the similarity of the CHIP managed care program to the Medicaid managed care program. We believe MLR calculation and reporting are important tools to ensure that the CHIP program is administered in an effective and efficient manner in accordance with section 2101(a) of the Act.

This is the only standard we propose to adopt from § 438.4. We do not propose to adopt any of the other Medicaid standards related to rate development (§ 438.5), contract provisions related to payment (§ 438.6), or rate certification (§ 438.7).

To effectuate the medical loss ratio described in § 457.1203(c), we propose to align with the Medicaid proposed regulations at § 438.8 and § 438.74.

6. Non-Emergency Medical Transportation PAHPs (§ 457.1206)

We believe states may use a PAHP structure to deliver non-emergency medical transportation (NEMT) services in CHIP as is done in Medicaid. As such, we propose to adopt the Medicaid approach to regulating NEMT PAHPs. However, if a state chooses to use a PAHP to provide NEMT services along with any other ambulatory medical service, that PAHP will then be considered a traditional PAHP as defined in § 457.10 and all the PAHP provisions throughout subpart L of this part will apply.

At § 457.1206, we propose to largely adopt § 438.9, which sets out the standards that apply to PAHPs that provide only NEMT services. The only difference between § 438.9 and § 457.1206 is that we have not included standards related to advance directives, and long-term services and supports, because we have not adopted these standards in CHIP. Instead of requiring actuarial soundness, we propose to require that NEMT PAHPs follow the standards of § 457.1203 related to rate development standards.

7. Information Requirements (§ 457.1207)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the provision of information standards at section 1932(a)(5) apply to CHIP managed care programs. As such, we are proposing to align CHIP with Medicaid information standards at § 438.10, which effectuate section 1932(a)(5) of the Act. We propose adding § 457.1207, which provides that states must require CHIP MCOs, PAHPs, PIHPs, PCCMs, and PCCM entities to provide enrollment notices, informational materials and instructional materials relating to enrollees and potential enrollees as provided in § 438.10. Including the cross reference to Medicaid managed care information standards supports CMS' goal to align and maximize coordination between insurance affordability programs. The proposed revisions include a more structured and coherent set of state and managed care plan standards for beneficiary information, and permit the availability of beneficiary information in electronic form. In this way, we propose to align CHIP and managed care beneficiary information dissemination practices with those of Medicaid and the commercial insurance market.

8. Requirement Related to Indians, Indian Health Care Providers, and Indian Managed Care Entities (§ 457.1208)

Section 2107(e)(1)(M) of the Act, as added by section 5006 of ARRA, specifies that the provisions related to managed care contracts that involve Indians, Indian health care providers (IHCP), and Indian managed care entities (IMCE) at sections 1932(a)(2)(C) and 1932(h) of the Act apply to CHIP. As such, we are proposing to align CHIP with Medicaid when MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities enroll Indians at § 438.14, which effectuate sections 1932(a)(2)(C) and 1932(h) of the Act.

9. Managed Care Enrollment (§ 457.1210), Disenrollment (§ 457.1212), and Continued Services to Beneficiaries (§ 457.1216)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the enrollment, termination of enrollment, and change in enrollment provisions at section 1932(a)(4) of the Act apply to CHIP managed care programs.

Related to enrollment, we propose adding § 457.1210. The proposed regulation closely follows the statutory language of section 1932(a)(4)(C) and (D) of the Act, setting out the standards for states that use the default enrollment process in paragraph (a), and ensuring the process prioritizes continuity of coverage in paragraph (b). This approach is similar to current Medicaid managed care regulations in § 438.50(e) and (f). Although section 1932(a)(4)(D) of the Act appears to require states to set up a default enrollment process, that paragraph is qualified by a reference to section 1932(a)(1) of the Act—namely the phrase ''in carrying out paragraph (a)(1),''—but section 1932(a)(1) of the Act has not been incorporated into the CHIP statute. As a result, we do not propose to require states to set up a default process for CHIP. However, we seek comment on whether the CHIP provision that incorporates section 1932(a)(4)(D) of the Act should instead be read in a manner that requires states to establish a default enrollment process.

The proposed CHIP regulation deviates from the Medicaid managed care proposed regulation at § 438.54. There, Medicaid proposes standards for several enrollment processes, including requiring that states provide at least 14 days for potential enrollees to make an active choice of a managed care plan. Discussion of the rationale for the changes to the Medicaid regulations can be found in section I.B.5.a of this proposed rule. We considered adopting the Medicaid approach, but ultimately decided that it was not well suited to CHIP because of the historic flexibility granted to states in administering the program. In addition, CHIP enrollment is often prospective, so children are not enrolled in the program until they have selected a managed care plan and, if applicable, paid a premium. In a state that uses prospective enrollment, requiring a 14-day choice period would delay coverage. We also considered developing enrollment standards based on the type of delivery system used in the state (FFS, managed care, or both). We seek comment on our proposed approach to enrollment and any alternatives.

Related to disenrollment, we propose adding § 457.1212, which implements section 1932(a)(4)(A) and (B) of the Act. The proposed regulation would provide that states must follow, and ensure MCOs, PAHPs, PIHPs, PCCMs, and PCCM entities follow, the Medicaid disenrollment standards provided at § 438.56. It is important to note that because section 1932(a)(4) of the Act gives individuals the right to disenroll from their managed care entity (MCE) while still remaining eligible to receive benefits, the state must contract with at least two MCEs, or contract with one MCE and operate an alternate delivery system, such as FFS, to provide CHIP benefits to those who have disenrolled from the state's contracted MCE. To meet the statutory disenrollment standards, a state currently providing CHIP benefits through one delivery system (for example, managed care) could either contract with at least two MCEs, establish a FFS option, or contract with some, or all, of the state's existing Medicaid provider network. While section 403 of CHIPRA applies the disenrollment standards set forth in section 1932(a)(4) of the Act, it did not apply the choice of MCE standard in section 1932(a)(3) of the Act; therefore, the state does not need to offer alternative delivery systems at the time of enrollment but only in the event an enrollee disenrolls from the state's contracted MCE.

Finally, related to change in enrollment, we propose adding § 457.1216, which provides that states must follow the Medicaid standards related to continued services to enrollees at § 438.62, for the same reasons we propose to adopt such standards for Medicaid managed care plans. Further discussion related to our rationale for adopting these standards can be found in the preamble discussion of the Medicaid standard at I.B.5.e.

10. Conflict of Interest Safeguards (§ 457.1214)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the conflict of interest provisions at section 1932(d)(3) of the Act apply to CHIP managed care programs. As such, we are proposing to align CHIP with Medicaid conflict of interest safeguards at § 438.58, which effectuate section 1932(d)(3) of the Act. We propose adding § 457.1214, which provides that states have safeguards against conflict of interest as provided in § 438.58.

11. Network Adequacy Standards (§ 457.1218)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that that the provisions at section 1932(a)(5) of the Act, requiring that MCEs assure adequate capacity to serve the expected enrollment, apply to CHIP managed care programs. As such, we are proposing to align CHIP with Medicaid network adequacy standards at § 438.68, which effectuate section 1932(a)(5) of the Act. We propose adding § 457.1218, which provides that states have network adequacy standards and ensure that managed care entities meet such standards as provided in

§ 438.68. Acknowledging that CHIP serves a child-focused population, we seek comment on whether we should include additional standards for additional pediatric providers, for example children's hospitals or child and adolescent behavioral health providers.

12. Enrollee Rights (§ 457.1220)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the enrollee rights provisions at section 1932(a)(5)(B)(ii) of the Act apply to CHIP managed care programs. As such, we are proposing to align CHIP with Medicaid enrollee rights provisions at § 438.100, which effectuate section 1932(a)(5)(B)(ii) of the Act. We propose adding § 457.1220, which provides that states must ensure that MCOs, PAHPs, PIHPs, PCCMs, and PCCM entities follow the enrollee rights standards as provided in § 438.100.

13. Provider-Enrollee Communication (§ 457.1222)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the enrollee rights provisions at section 1932(b)(3) of the Act apply to CHIP managed care programs. As such, we are proposing to align CHIP with Medicaid's enrollee rights protections of communications between providers and enrollees at § 438.102, which effectuate section 1932(b)(3) of the Act. We propose adding § 457.1222, which provides that states must ensure that MCOs, PAHPs, and PIHPs protect communications between providers and enrollees as provided in § 438.102.

14. Marketing Activities (§ 457.1224)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the restrictions on marketing at section 1932(d)(2) of the Act apply to CHIP managed care programs. As such, we are proposing to align CHIP with Medicaid standards related to marketing at § 438.104, which effectuate section 1932(d)(2) of the Act. We propose adding § 457.1224, which provides that states must ensure that MCOs, PAHPs, PIHPs, PCCMs, and PCCM entities follow the standards of § 438.104. This proposed rule is not intended to limit QHP issuers who are also CHIP managed care plans from marketing QHPs to the parents of CHIP eligible children. The proposed definition of marketing in § 438.104(a), as adopted in § 457.1224, excludes the communication to a CHIP beneficiary from the issuer of a QHP. Therefore, a QHP issuer that also operates a CHIP managed care plan would not be prohibited from contacting a family about QHP coverage. Indeed, we recognize that there may be benefit to the family from being informed about the availability of coverage through the Marketplace and selecting a carrier who offers both types of products.

We acknowledge that plan marketing has historically played a unique role in CHIP (for example, in some states plans have been allowed to directly enroll children into CHIP). Therefore, we seek comment on whether our proposed approach is appropriate, or whether we should take an alternate approach, for example by following the QHP marketing regulations at 45 CFR 156.225 or adopting a subset of the Medicaid regulations. We also seek comment on our proposal to apply to CHIP the standard at § 438.104(c) that the state must consult with the Medical Care Advisory Committee or an advisory committee with similar membership.

15. Liability for Payment (§ 457.1226)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the protections for enrollees against liability for payment at section 1932(b)(6) apply to CHIP managed care programs. As such, we are proposing to align CHIP with Medicaid liability protections at § 438.106, which effectuate section 1932(b)(6) of the Act. We propose adding § 457.1226, which provides that states must ensure that MCOs, PAHPs, and PIHPs do not hold enrollees liable for services or debts of the MCO, PAHP, and PIHP as provided in § 438.106.

16. Emergency and Poststabilization Services (§ 457.1228)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the standard that MCEs provide emergency and poststablization services at section 1932(b)(2) of the Act apply to CHIP managed care programs. As such, we are proposing to align CHIP with the Medicaid emergency and poststablization services standard at § 438.114, which effectuate section 1932(b)(2) of the Act. We propose adding § 457.1228, which provides that states must ensure that MCOs, PAHPs, and PIHPs make emergency and poststablization services available, and that the state make emergency and poststablization services available to enrollees of PCCMs and PCCM entities, as provided in § 438.114.

17. Access Standards (§ 457.1230)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the quality assurance standards at section 1932(c) of the Act apply to CHIP managed care programs. Section 1932(c)(1) of the Act requires states that contract with managed care organizations to develop and implement a quality assessment and improvement strategy, including standards related to access standards. Such access standards include the availability of services, assurances of adequate capacity and services, coordination and continuity of care, and coverage and authorization of services. As such, we are proposing to align CHIP with Medicaid availability of services standards at § 438.206, § 438.207, § 438.208, and § 438.210, which implement section 1932(c)(1) of the Act.

We propose adding § 457.1230(a), which provides that states must require CHIP MCOs, PAHPs, and PIHPs to ensure that covered services are available and accessible to enrollees as provided in § 438.206. At § 457.1230(b), we propose that states must ensure that CHIP MCOs, PAHPs, and PIHPs have adequate capacity to serve expected enrollees as provided in § 438.207. At § 457.1230(c), we propose that states must ensure that CHIP MCOs, PAHPs, and PIHPs comply with the coordination and continuity of care standards as provided in § 438.208. In proposing this alignment, we recognize the importance of care coordination when beneficiaries move between managed care entities and between settings, however we seek comment on the applicability of the Medicaid managed care standards in § 438.208 to the CHIP population.

Finally, at § 457.1230(d), we propose that states must ensure that CHIP MCOs, PAHPs, and PIHPs comply with some of the coverage and authorization of services standards as provided in § 438.210. There are several paragraphs of § 438.210 that we do not propose to adopt; however, we seek comment on this approach. Specifically, we do not propose to adopt the standards related to medically necessary services in § 438.210(a)(5), because title XXI of the Act does not include a requirement to provide medically necessary services. In addition, we do not propose to adopt the time frames for decisions in § 438.210(d). Instead, we propose to follow the time frames described in § 457.1160. We also seek comment on whether we should create and exception for § 438.210(b)(2)(iii) related to authorizing LTSS based on an enrollee's current needs assessment and consistent with the person-centered service plan should apply to CHIP, since it is not a required service and few separate CHIP programs provide this service.

18. Structure and Operation Standards (§ 457.1233)

Section 1932(c)(1) of the Act related to the development and implementation of a quality assessment and improvement strategy also includes standards related to the structure and operation of managed care contracts. We are proposing to align CHIP with Medicaid structure and operation standards at § 438.214 related to provider selection and § 438.230 related to subcontractual relationships and delegation, which effectuate section 1932(c)(1) of the Act. We propose adding § 457.1233(a) for provider selection and § 457.1233(b) for subcontractual relationships and delegation.

The standard under section 1932(c)(1) of the Act related to the development and implementation of a quality assessment and improvement strategy, also includes measurement and improvement standards. We are proposing to align CHIP with Medicaid standards at § 438.236 and § 438.242 which implement section 1932(c)(1) of the Act. We propose adding § 457.1233(c) related to practice guidelines as provided in § 438.236 and adding § 457.1233(d) related to health information systems as provided in § 438.242. Including the cross references to Medicaid quality assessment and improvement strategy standards supports CMS' goal to align insurance affordability program rules. We have elected not to propose that rules for CHIP align with the Medicaid confidentiality provision as set forth in § 438.224 because there is an existing confidentiality requirement at § 457.1110, which we believe is sufficient to address this standard.

19. Quality Measurement and Improvement (§ 457.1240, § 457.760)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that section 1932(c) of the Act applies to CHIP managed care programs. As such, we are proposing to align CHIP with Medicaid quality measurement and improvement standards at § 438.310, which implement section 1932(c) of the Act. We propose adding § 457.1240(a), to align with the scope set forth in § 438.310, which outlines standards for a quality assessment and performance improvement program that states must require of each contracting MCO, PIHP, or PAHP. At § 457.1240(b), we propose that states must ensure that CHIP MCOs, PIHPs or PAHPs have an ongoing comprehensive quality assessment and performance improvement program for the services it furnishes to enrollees as set forth in § 438.330. Section § 438.330 also references standards for LTSS, which we propose to apply to CHIP to align with the Medicaid standards. We seek comments on the appropriateness of applying this standard for the CHIP program. At § 457.1240(c), we propose that states must review and approve the performance of each MCO, PIHP, and PAHP in accordance with the requirements set forth in § 438.332. At § 457.1240(d), we propose that states must collect data and apply the methodology established under the process described in § 438.330(a)(2) to determine a Managed Care rating or ratings for each CHIP MCO, PIHP, and PAHP in accordance with the standards set forth in § 438.334. At § 457.1240(e), we propose the managed care elements of the state comprehensive quality strategy for assessing and improving the quality of managed care services provided by CHIP MCOs, PIHPs, and PAHPs as set forth in § 438.340. Finally, at § 457.760, we propose that states must incorporate CHIP into their state comprehensive quality strategy that establishes the minimum standards inclusive of all delivery systems as set forth in § 431 subpart I. We considered whether CHIP could have its own comprehensive quality strategy, but determined that it would be more efficient and promote alignment of quality improvement to include CHIP in a single, state comprehensive quality strategy that includes all children in Medicaid and CHIP. We seek comment on this approach.

20. External Quality Review (§ 457.1250)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the external quality review standards at section 1932(c) of the Act apply to CHIP managed care programs. Section 1932(c)(2) of the Act requires external independent review of managed care activities. As such, we are proposing to align CHIP with Medicaid external quality review standards at § 438.350, which effectuate section 1932(c)(2) of the Act. Currently, funding for CHIP quality activities would be limited to the ten percent administrative expenditures allotted for non-primary services as set forth in § 457.618. We seek comments on any issues this may present to implementing these standards. We propose adding § 457.1250(a), which requires each state that contracts with MCOs, PIHPs or PAHPs follow all applicable external quality review standards as set forth in §§ 438.350, 438.352, 438.354, 438.356, 438.358, and 438.364. We do not adopt any provision related to plans serving dual eligible populations, because CHIP does not have such populations. At § 457.1250(b), we outline the provisions that do not apply to the CHIP external quality review process for states contracting with MCOs, PIHPs or PAHPs, including the nonduplication of mandatory activities at § 438.360 and the exemption from external quality review at § 438.362. CHIP elected not to align with the Medicaid exemption from EQR as set forth in § 438.362. This provision specifies that, if an MCO, PIHP, or PAHP has a current Medicare contract under part C of Title XVIII or under section 1876 of the Act, and a current Medicaid contract under section 1903(m) of the Act, the state may exempt them from EQR if all the conditions are met. The MCO, PIHP, or PAHP must submit the findings from the Medicare report to meet this standard. This would not be applicable to CHIP, as the findings through Medicare would not include children. We also propose allowing states to amend current external quality review contracts to add CHIP as long as the existing contract meets standards outlined in § 438.356. Adding the cross references to Medicaid quality measurement and improvement and external quality review standards to CHIP will help achieve the goal of increased program alignment and streamlined processes.

21. Grievances (§ 457.1260)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA, specifies that the grievance provision at section 1932(b)(4) of the Act apply to CHIP managed care programs. As such, we are proposing to align CHIP with the Medicaid grievance and appeals sections at subpart F of part 438, which implement section 1932(b)(4) of the Act. We propose adding § 457.1260, which provides that states must ensure that MCOs, PAHPs, and PIHPs comply with subpart F of part 438, with two exceptions. First, we do not propose to adopt § 438.420, which requires continuation of benefits pending appeal. We considered following Medicaid by requiring benefits to continue pending appeal, but CHIP has not previously had this standard, so we decided not to extend it to CHIP managed care through this rule. We seek comment on this approach. The second deviation from Medicaid is that we note that, in the CHIP context, references to fair hearings should be read as references to reviews as described in subpart K of part 457.

22. Sanctions (§ 457.1270)

Section 2103(f)(3) of the Act, as amended by section 403 of CHIPRA,

specifies that the sanctions provisions at section 1932(e) of the Act apply to CHIP managed care programs. As such, we are proposing to align CHIP with the Medicaid sanctions sections at subpart I of part 438, which effectuate section 1932(e) of the Act. We propose adding § 457.1270, which provides that states must ensure that MCOs, PAHPs, and PIHPs comply with the sanctions standards as provided in subpart I of part 438.

23. Program Integrity—Conditions Necessary to Contract as an MCO, PAHP, or PIHP (§ 457.955, § 457.1280, and § 457.1285)

Section 2107 of the Act includes several program integrity standards, including sections 2107(b), 2107(e)(1)(D), and 2107(e)(2). We propose to effectuate those standards by adopting many of the Medicaid program integrity standards in CHIP. In addition, we propose to maintain but relocate the current CHIP regulations related to managed care program integrity.

We propose to redesignate all of § 457.955 to § 457.1280. This section is currently located in the general CHIP program integrity subpart I. Because the section specifies conditions necessary for entities to contract as an MCO, PAHP, PIHP, we propose to move it to the new subpart L where the other managed care regulations will be located. We propose several minor changes to the regulation text: (1) To update references to MCE to MCO, PAHP, or PIHP; (2) to add at paragraph (b)(1) that MCOs, PAHPs, and PIHPs must comply with applicable state and Federal statutes and regulations, in addition to complying with state and Federal standards; (3) and to add at paragraph (b)(3) that there must be mechanisms for MCOs, PAHPs, and PIHPs to report providers to the state.

We also propose to adopt nearly all of the of the several Medicaid program integrity standards. In § 457.1285, we propose to adopt subpart H of part 438, with the exception of § 438.604(a)(2), which does not apply because we are not proposing to adopt for CHIP all of the Medicaid actuarial soundness requirements.

III. Third Party Liability

A. Background

Title XIX of the Act requires State Medicaid programs to identify and seek payment from liable third parties, before billing Medicaid. Specifically, section 1902(a)(25)(A) of the Act mandated states ''take all reasonable measures to ascertain legal liability of third parties . . . to pay for care and services available under the plan.''

Under section 1902(a)(25)(A) of the Act, a third party is any individual, entity, or program that is or may be liable to pay all or part of the expenditures for medical assistance furnished under a State plan. Medicaid is intended to be the payer of last resort; that is, other available resources must be used before Medicaid pays for the care and services of a Medicaid-eligible individual. These other resources are known as third party liability, or TPL.

Further provisions under section 1902(a)(25)(A)(i) of the Act specify that the Medicaid State plan must provide for the collection of sufficient information to enable the State to pursue claims against third parties. Examples of liable third parties include commercial insurance companies through employment-related or privately purchased health insurance; casualty coverage resulting from an accidental injury; payment received directly from an individual who has either voluntarily accepted or assigned legal responsibility for the health care of one or more Medicaid recipients; and fraternal groups, union, or State workers' compensation commissions. Third Party Liability also includes medical support provided by a parent under a court or administrative order.

To support identification of TPL and with the authority granted in section 1902(a)(25)(A), in 1987, we (then the Health Care Financing Administration [HCFA]) issued regulations at § 433.138 establishing requirements for State Medicaid agencies to obtain information via data matching with the state Workers Compensation files or state Motor Vehicle Accident Report. Additionally, states are required to identify all paid claims (indicative of trauma), identified by diagnosis codes found in ICD–9–CM, 800 through 999, except 994.6.

Section 433.138(e) specifically references the use and application of the ICD–9–CM medical coding system, to assist in identifying liable third parties as primary payers before Medicaid. However, by 1990, HCFA realized it might have been too prescriptive to require states to review all ICD–9–CM trauma codes, and amended § 433.138 to allow states to submit waiver requests to cease editing codes proven to be unproductive in identifying liable third parties. States now have over 25 years of experience identifying trauma codes indicating third party liability, which contributes to payment of Medicaid expenses.

In 1990, the World Health Organization (WHO) approved the 10th Revision of the International Classification of Diseases (ICD), which is known as ICD–10. The Secretary adopted the ICD–10 medical code sets effective March 17, 2009, and all Health Insurance Portability and Accountability Act covered entities are required to use ICD–10 to code health services provided on or after its compliance date of October 1, 2015 (ICD–10's compliance date was previously delayed; the October 1, 2015 compliance date is specified at 79 FR 45128 (Aug. 4, 2014)).

B. Provisions of the Proposed Regulations

Section 433.138(e) mandates the use of ICD 9–CM coding, which is due to be replaced by ICD–10 coding for coding health services provided on October 1, 2015. Section 433.138(e) obliges states to comply with the soon to be replaced ICD–9–CM coding system; thus references to ICD–9–CM specific codes need to be removed from the regulation. We considered ways to best achieve this aim, keeping in mind that states bear the responsibility for interpreting and applying the increased number of new ICD–10 codes and that State Medicaid programs need greater discretionary authority in developing trauma code edits to best identify liable third parties and achieve the highest TPL return from their efforts.

In considering how best to amend the regulation we reviewed our previous amendments, which demonstrated a progression from explicit federally-prescribed requirements to less prescriptive approaches that, while maintaining the federal designation of trauma codes subject to review, allowed states to propose waivers of editing for trauma codes that were not cost-effective to pursue.

This regulation was last amended in 1995 to remove trauma code-specific waiver authority from § 433.138(e) and add § 433.138(l) to federal regulations, establishing the possibility of waiver of non-statutory requirements in § 433.138 and § 433.139, including § 433.138(e). States could request adjustments to any of several non-statutory requirements, including the code editing requirements, if they determined the activity to not be cost-effective. Section 433.138(l) specified that an activity would not be cost-effective if the cost of the required activity exceeds the third party liability recoupment and the required activity accomplishes, at the same or at a higher cost, the same objective as another activity that is being performed by the state.

The background information in the preamble for the regulatory amendment

published in the **Federal Register** on July 10, 1995 (60 FR 35498 through 35503) affirmed that we had been prescriptive in the initial 1987 regulations for trauma code editing, explaining that TPL was then in its ''infancy'' and there was concern that states were not identifying instances of traumatic injury for which a liable third party might exist. By 1995, when the last amendment to the trauma code was proposed, we acknowledged that states had other means of identifying potential TPL for trauma cases, including federally-required data matches with state motor vehicle administration accident files and with state worker's compensation files, and that ''the majority of states have aggressive and comprehensive TPL programs.''

It has been almost 20 years since we last amended the regulations for trauma code editing and during that time, states' information technology systems have greatly improved and state TPL programs have refined procedures to identify instances when a Medicaid beneficiary's traumatic injury may lead to identification of a liable third party.

The proposed amendment to § 433.138(e), which removes references to ICD–9–CM, offers us an opportunity to make a substantive change to this regulation while still affirming the continuing responsibility of state Medicaid programs to identify trauma-related claims to determine TPL and ensure that state Medicaid programs remain secondary payers as specified in federal law. Therefore, we propose to replace the reference to a specific coding system with a general description of the types of medical diagnoses indicative of trauma for which states are expected to edit claims. We believe this revision will allow states greater flexibility to focus on identification of claims likely to have TPL.

This amendment does not propose that any state change its current trauma code editing process with regard to codes that the state has identified as not being productive of third party recoveries and that CMS has agreed the state may discontinue editing. We recognize that states now have over 25 years of experience related to identifying trauma codes that are likely to have a responsible third party and generating recoveries. This amendment affords states the opportunity to revise their trauma code editing processes with regard to identifying nonproductive codes if and when they deem necessary.

Therefore, in § 433.138(e)(1), we propose to remove the reference to the ICD–9–CM code range 800 through 999. This code range defined the codes that were indicative of traumatic injury. States had to follow-up on these codes, unless that requirement was specifically waived, to identify potentially liable third parties. The ICD–9–CM coding system and codes will shortly be replaced by the ICD–10 coding system and codes, which has an October 1, 2015 compliance date. The narrative statement will have greater longevity, as it is not tied to any one edition of the ICD coding system or any other coding system that the Secretary of DHHS may adopt in the future.

We have retained the regulatory references to complete trauma code editing and to the possibility of a state's pursuing waiver of the requirements of the regulation, to allow the state to request a waiver of the regulatory standards, if the state wishes to adjust its trauma code editing process beyond the scope allowed by these changes to § 433.138(e).

We propose to also remove § 433.138(e)(2), as the regulation specifically refers to exclusion of the ICD–9–CM code for motion sickness and we propose to revise § 433.138 to remove all references to ICD–9–CM-specific coding.

Removing paragraph (e)(2) of § 433.138(e) eliminates the necessity to identify the remaining regulatory text as § 433.138(e)(1), so we have eliminated the paragraph (e)(1) designation from the revised § 433.138(e).

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We are soliciting public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs) in this proposed rule.

A. Background

The burden associated with the requirements under parts 431 and 438 is the time and effort it would take each of the Medicaid programs to comply with this rule's proposed requirements. This rule would revise the Medicaid managed care regulations to implement statutory provisions, strengthen actuarial soundness and other payment regulations improving accountability of rates paid in the Medicaid managed care program, implement changes supporting alignment with other public and insurance affordability programs, strengthen beneficiary protections, and modernize the regulations recognizing changes in usage of managed care delivery systems since the release of the part 438 final rule in 2002.

Section 433.138(e)(1) would make a technical correction addressing state Medicaid agencies' review of claims with trauma codes, to identify instances where third party liability (TPL) may exist for expenditures for medical assistance covered under the state plan. The correction would remove references to the International Classification of Disease, 9th edition, Clinical Modification Volume 1 (ICD–9–CM) by replacing the references with a general description of the types of medical diagnoses indicative of trauma. States would use the International Classification of Disease that they are using at the time of claims processing. There is no additional cost to the state related to the proposed regulation changes to § 433.138(e) because the proposed changes do not require any action by the state, if the state wishes to continue editing for the same types of traumatic injuries currently identified with ICD–9–CM codes after the conversion of the claims processing system to ICD–10 codes. Further, since trauma code editing is based on current MMIS claims processing, revisions to accommodate the coding system change from ICD–9–CM to ICD–10 are already in progress as a required adjustment of each state's MMIS. This proposed rule allows states to make adjustments to certain TPL activities without preparing a formal waiver request to seek CMS's permission. There is no requirement for a state to make such adjustments.

We propose adding a new subpart L to part 457, which will contain the regulations related to CHIP managed care plans. Most of the proposed regulations in this subpart are new, however we also propose to move portions of § 457.950 and all of § 457.955 from subpart I to the new subpart. This will ensure that all related information is contained in one subpart.

B. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2013 National Occupational Employment and Wage Estimates for all salary estimates (*www.bls.gov/oes/current/oes_nat.htm*). Table 1 presents the median hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 1—OCCUPATION TITLES AND WAGE RATES

Occupation title	Occupation code	Mean hourly wage	Fringe benefit (at 100%)	Adjusted hourly wage
Accountant	13–2011	$31.55	$31.55	$63.10
Actuary	15–2011	46.00	46.00	92.00
Business Operations Specialist	13–1000	29.66	29.66	53.32
Computer Programmer	15–1131	36.80	36.80	73.60
Customer Service Rep	43–4051	14.84	14.84	29.68
General and Operations Mgr	11–1021	63.86	63.86	127.72
Healthcare Social Worker	21–1022	29.60	29.60	59.20
Mail Clerk	43–9051	13.20	13.20	26.40
Office and Administrative Support Worker	43–9000	14.96	14.96	29.92
Registered Nurse	29–1141	32.70	32.70	65.40

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

C. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding State Comprehensive Quality Strategy (§ 431.502)

Under § 431.502 all 56 states and territories (referred to throughout this section as ''states'') would have and operate a comprehensive quality strategy for all Medicaid beneficiaries in the state regardless of delivery system. This would replace the quality strategy focused exclusively on Medicaid managed care which currently exists at § 438.202.

Per § 431.502(a) each state would write and implement a comprehensive quality strategy. We estimate that drafting an initial state comprehensive quality strategy would take 70 hr at $53.32/hr for a business operations specialist to develop the proposed strategy, 2 hr at $29.92/hr for an office and administrative support worker to publicize the strategy, 15 hr at $53.32/hr for a business operations specialist to review and incorporate public comments into the strategy, and 1 hr at $29.92/hr for an officer and administrative support worker to submit the initial quality strategy to CMS. We also estimate that 19 states would draft an initial comprehensive quality strategy (as the other 37 states already have an initial quality strategy). In aggregate, we estimate a one-time burden of 1,672 hr (19 states × 88 hr) and $87,817.24 [19 states × ((85 hr × $53.32/hr) + (3 hr × $29.92/hr))] for states to develop initial comprehensive quality strategies and submit them to CMS.

2. ICRs Regarding State Comprehensive Quality Strategy Development, Assessment, and Revision (§ 431.504)

Section 431.504(a) would have states engage the public in the development of the comprehensive quality strategy. The burden associated with this process is captured in § 431.502 for the initial comprehensive quality strategy.

In accordance with proposed § 431.504(b), states would review and revise their comprehensive quality strategies as needed, but no less frequently than once every 3 years. While the 37 states that contract with MCOs and/or PIHPs currently revise their quality strategies periodically, approximately half of those states (18) revise their quality strategies less frequently that proposed.

We estimate a burden for the revision of a comprehensive quality strategy of, once every 3 years, 25 hr at $53.32/hr for a business operations analyst to review and revise the comprehensive quality strategy, 2 hr at $29.92/hr for an office and administrative support worker to publicize the strategy, 5 hr at $53.32/hr for a business operations specialist to review and incorporate public comments, and 1 hr at $29.92/hr for an office and administrative support worker to submit the revised quality strategy to CMS. In aggregate, we estimate an ongoing annualized state burden of 198 hr [(18 states × (33 hr)/3 years] and $10,136.16 [(18 states × ((30 hr × $53.32/hr) + (3 hr × $29.92/hr)))/3 years].

The revision of a comprehensive quality strategy would be a new process for the 19 states that do not currently contract with MCOs and/or PIHPs. We estimate that those states would need 0.5 hr at $53.32/hr for a business operations specialist to revise their policies and procedures. In aggregate, we estimate a one-time state burden of 9.5 hr (19 states × 0.5 hr) and $506.54 (9.5 hr × $53.32/hr) to update policies and procedures.

We assume that it will be less burdensome to revise an existing comprehensive quality strategy than to draft an initial strategy. Therefore, we estimate a burden for the comprehensive quality strategy revision process, once every 3 years, of 25 hr at $53.32/hr for a business operations analyst to review and revise the comprehensive quality strategy, 2 hr at $29.92/hr for an office and administrative support worker to publicize the strategy, 5 hr at $53.32/hr for a business operations specialist to review and incorporate public comments, and 1 hr at $29.92/hr for an office and administrative support worker to submit the revised quality strategy to CMS. In aggregate, we estimate an ongoing annualized state burden of 209 hr [(19 states × (33 hr)/3 years] and $10,699.28 [(19 states × ((30 hr × $53.32/hr) + (3 hr × $29.92/hr)))/3 years].

Of the 37 states that contract with MCOs and/or PIHPs, we estimate that 10 states already have a comprehensive quality strategy. This could be due to a variety of reasons, such as the special terms and conditions of a section 1115 demonstration or in response to SHO Letter #13–007. The remaining 27 states would, at their next revision, transition

from a quality strategy to a comprehensive quality strategy. We estimate that this would pose a burden of 10 hr at $53.32/hr for a business operations specialist at the next revision. In aggregate, we estimate a one-time state burden of 270 hr (27 states × 10 hr) and $14,396.40 (270 hr × $53.32/hr).

We propose in section § 431.504(b)(1) that the review of the comprehensive quality strategy would include an effectiveness evaluation conducted within the previous 3 years. We estimate the burden of this evaluation at 40 hr at $53.32/hr for a business operations specialist once every 3 years for all 56 states. The currently approved burden estimates that creating and submitting an implementation and effectiveness report to CMS for the 37 states with MCOs and/or PIHPs takes 40 hr per state once every 3 years. In its place, the review of the comprehensive quality strategy (including the effectiveness evaluation) would apply to the 56 states but the burden increase would apply to the remaining 19 states. In aggregate, we estimate an ongoing annualized burden of 253.3 hr [(19 states × 40 hr)/3 years] and $13,505.96 (253.3 hr × $53.32/hr) to evaluate the effectiveness of a comprehensive quality strategy.

States would post the effectiveness evaluation on the state's Medicaid Web site under proposed § 431.504(b)(2). While this standard is subject to the PRA, we believe the associated burden is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with the aforementioned standards would be incurred by persons during the normal course of their activities and, therefore, should be considered a usual and customary business practice.

As described in § 431.504(c), states would submit to CMS a copy of the initial comprehensive quality strategy and any subsequent revisions. The burden associated with this standard has been captured in §§ 431.502(a) (initial strategy) and 431.504(b) (revision of strategy). As this would be a new standard for the 19 states that do not currently contract with MCOs and/or PIHPs, we believe that these states would need to modify their policies and procedures to incorporate this action. We estimate a burden of 0.5 hr $53.32/hr for a business operations specialist. In aggregate, we estimate a one-time state burden of 9.5 hr (19 states × 0.5 hr) and $506.54 (9.5 hr × $53.32/hr).

Finally, § 431.504(d) would have states post the final comprehensive quality strategy to their Medicaid Web sites. While this standard is subject to the PRA, we believe the associated burden is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with the aforementioned standards would be incurred by persons during the normal course of their activities and, therefore, should be considered a usual and customary business practice.

3. ICRs Regarding Standard Contract Requirements (§§ 438.3, 438.10(c)(5), 438.14(b), 438.110(a), 438.210(b)(2)(iii), 438.242(c), 438.402 and 438.608)

Section 438.3 contains a list of provisions that must be included in MCO, PIHP, PAHP, HIO, and/or PCCM contracts. While the burden associated with the implementation and operation of the contracts is set out when warranted under the appropriate CFR section, the following burden estimate addresses the effort to amend existing contracts. The estimate also includes the burden for additional contract amendments that would be required under:

- § 438.10(c)(5) would require specific information to be provided to enrollees.
- § 438.14(b) would specify requirements for Indian enrollees and providers.
- § 438.110(a) would require the establishment and maintenance of member advisory committees.
- § 438.210(b)(2)(iii) would require LTSS to be authorized consistent with the enrollee's needs assessment and person centered plan.
- § 438.242(c) would require specific provisions for encounter data.
- § 438.608 would require administrative and management arrangements and procedures to detect and prevent fraud, waste, and abuse.

We estimate a one-time state burden of 6 hr at $53.32/hr for a business operations specialist to amend all contracts. In aggregate, we estimate 3,612 hr (602 contracts × 6 hr) and $192,591.84 (3,612 hr × $53.32/hr).

4. ICRs Regarding Rate Standards (§ 438.5)

Section 438.5 describes CMS' proposal related to the development and documentation of capitation rates paid to risk-based MCOs, PIHPs and PAHPs. Generally, we would require: The use of appropriate base data; application of trends that have a basis in actual experience; a comprehensive description of the development of the non-benefit component of the rate; descriptions of the adjustments applied to the base data, rate, or trends; actuarial certification of the final contract rates paid to the plans; and a description of budget neutral risk adjustment methodologies.

We believe that the requirements related to the use appropriate base data and the adequate description of rate setting standards, such as trend, the non-benefit component, adjustments, and risk adjustment, are already required as part of actuarial standards of practice and accounted for in § 438.7. We clarified that risk adjustment should be done in a budget neutral manner, but the manner in which risk adjustment is applied should not create additional burden on the state.

In § 438.5(g), the certification of final contract rates would place additional burden on the states. We estimate that most states currently certify a range as compared to the actual contract rate paid to the health plan. Therefore, out of the total 70 certifications submitted to CMS from 39 states, the process underlying 50 certifications will need to the modified.

We estimate it would take approximately 10 hr at $92/hr for an actuary and 1 hr at $127.72/hr for a general and operations manager to comply with this requirement. In aggregate, we estimate an annual state burden of 550 hr (50 certifications × 11 hr) and $52,386 [50 certifications × ((10 hr × $92/hr) + (1 hr × $127.72/hr))].

5. ICRs Regarding Rate Certification Submission (§ 438.7)

Section 438.7 describes the submission and documentation requirements for all managed care actuarial rate certifications. The certification will be reviewed and approved by CMS concurrently with the corresponding contract(s). Section 438.7(b) details CMS' expectations for documentation in the rate certifications. We believe these requirements would be in line with actuarial standards of practice and previous Medicaid managed care rules.

While the 2002 final rule (under § 438.6(c)) set out the burden per contract (15,872 hr based on 32 hr per plan), experience has shown that states do not submit certifications per plan. We believe a better estimation of the burden would be associated with the development of the rate certification. In this regard, we estimate it would take 230 hr to develop each certification, consisting of 100 hr (at $92/hr) for an actuary, 10 hr (at $127.72/hr) for a general and operations manager, 50 hr (at $73.60/hr) for a computer programmer, 50 hr (at $53.32/hr) for a business operations specialist, and 20 hr

(at $29.92/hr) for an office and administrative support worker.

The revised burden is based on a total of 16,100 hr (230 hr × 70 certifications) which would add 228 hr (16,100 hr − 15,872 hr) for all 70 certifications, adjusted to 3.3 hr per certification. In aggregate, we estimate an annual state burden of $17,852.41 [70 certifications × ((1.5 hr × $92/hr) + (0.13 hr × $127.72/hr) + (0.73 hr × $73.60/hr) + (0.73 hr × $53.32/hr) + (0.26 hr × $29.92/hr))].

6. ICRs Regarding Minimum Medical Loss Ratio (§ 438.8)

Section 438.8(c) would require that MCOs, PIHPs, and PAHPs report to the state annually their total expenditures on all claims and non-claims related activities, premium revenue, the calculated MLR, and, if applicable, any remittance owed.

We estimate total number of MLR reports that MCOs and PIHPs would be required to submit to the state would amount to 568 contracts. While the number of contracts includes 545 credible contracts and 23 non-credible contracts, all MCOs and PIHPs will need to report the information required under § 438.8 regardless of their credibility status.

We estimate a one-time private sector burden of 168 hr for the initial administration activities. We estimate that 60 percent of the time would be completed by a computer programmer (101 hr at $73.60/hr), 30 percent would be completed by a business operations specialist (50 hr at $53.32/hr), and 10 percent would be completed by a general and operations manager (17 hr at $127.72/hr). This amounts to $12,270.84 ((101 hr × $73.60) + (50 hr × $53.32) + (17 hr × $127.72)) per report or $6,969,837.12 (568 × $12,270.84) for 568 MCOs, PIHPs, and PAHPs in 2017 (the one-time burden).

In subsequent years, since the programming and processes established in 2017 will continue to be used, the burden will decrease from 168 hr to approximately 53 hr. Using the same proportions of labor allotment, we estimate an annual private sector burden of $3,846.92 per report and a total of $2,185,050.56 [568 contracts × $3,846.92 ((32 hr × $73.60/hr) + (16 hr × $53.32/hr) + (5 hr × $127.72/hr)]. We expect that states will permit MCOs, PIHPs, and PAHPs to submit the report electronically. Since the submission time is included in our reporting estimate, we are not setting out the burden for submitting the report.

7. ICRs Regarding Information Requirements (§ 438.10)

Section 438.10(c)(3) would require states to operate a Web site that provides the information required in § 438.10(f). Since states already have Web sites for their Medicaid programs and most also include information about their managed care program, most states would only have to make minor revisions to their existing Web site.

We estimate 6 hr at $73.60/hr for a computer programmer to make the initial changes. We also estimate 3 hr for a computer programmer to periodically add or update documents and links on the site. In aggregate, we estimate a one-time state burden of 252 hr (42 states × 6 hr) and $18,547.20 (252 hr × $73.60/hr). In subsequent years, we estimate an annual state burden of 126 hr (42 states × 3 hr) and $9,273.60 (126 hr × $73.60/hr).

Section 438.10(c)(4)(i) would recommend that states develop definitions for commonly used terms to enhance consistency of the information provided to enrollees. We estimate it would take 6 hr at $53.32/hr for a business operations specialist to develop these definitions. In aggregate, we estimate a one-time state burden of 252 hr (42 states × 6 hr) and $13,436.64 (252 hr × $53.32/hr).

Section 438.10(c)(4)(ii) would recommend that states create model enrollee handbooks and notices. Since many states already provide model handbooks and notices to their entities, we estimate 20 states may need to take action to comply with this provision. We estimate it would take 20 hr at $53.32/hr for a business operations specialist to create these documents. We also estimate 2 hr per year for a business operations specialist to revise these documents, if needed. In aggregate, we estimate a one-time state burden of 400 hr (20 states × 20 hr) and $21,328 (400 hr × $53.32/hr). In subsequent years we estimate an annual burden of 40 hr (20 states × 2 hr) and $2,132.80 (40 hr × $53.32/hr).

Section 438.10(d)(2)(i) would require that states add taglines to all printed materials for potential enrollees explaining the availability of translation and interpreter services as well as the phone number for choice counseling assistance. As the prevalent languages within a state do not change frequently, we are not estimating the burden for the rare updates that will be needed to update these taglines. We estimate it would take 2 hr at $53.32/hr for a business operations specialist to create the taglines and another 4 hr to revise all document originals. In aggregate, we estimate a one-time state burden of 252 hr (42 states × 6 hr) and $13,436.64 (252 hr × $53.32/hr).

Section 438.10(e)(1) clarifies that states can provide required information in paper or electronic format. As this is an existing requirement, the only burden change we estimate is adding two new pieces of information generated in § 438.68 (network adequacy standards) and § 438.330 (quality and performance indicators). We estimate 1 hr at $53.32/hr for a business operations specialist to update or revise existing materials and 1 min at $26.40/hr for a mail clerk to mail the materials to 5 percent of the enrollees that are new (3,135,242). In aggregate, we estimate a one-time state burden of 42 hr (42 states × 1 hr) and $2,239.44 (42 hr × 53.32/hr) to update/revise existing materials. The currently approved burden estimates 5 min per mailing for 65,000 total hr. By updating the enrollment figure to 2,069,259 (62,704,821 × .033) and reducing the time from 5 min to 1 min (to acknowledge automated mailing processes), we estimate the annual state burden for mailing as −30,512 hr (34,488 hr − 65,000 hr) and −$805,516.80 (−30,512 hr × $26.40/hr).

Section 438.10(g)(1) would require that MCOs, PIHPs, PAHPs, and PCCMs provide an enrollee handbook. Since § 438.10(g) has always required the provision of this information (although it did not specifically call it a ''handbook''), we believe only new managed care entities would need to create this document. Given the requirement in § 438.10(c)(4)(ii) for the state to provide a model template for the handbook, the burden on a new entity would be greatly reduced. It is not possible for us to estimate how many, if any, new managed care entities may contract with a state in any year. We invite comment on an appropriate average number of new plans each year. State burden to create the template for a model handbook is set out under § 438.10(c)(4)(ii).

For existing entities that already have a method for distributing the information, we believe that 100 entities will need to modify their handbook to comply with a new model provided by the state. We estimate 100 entities would rely on a business operations specialist to spend 4 hr at $53.32/hr to update their handbook. Once revised, the handbooks need to be sent to enrollees. We estimate 1 min by a mail clerk at $26.40/hr to send handbooks to 10,659,819 enrollees (17 percent of total enrollment). To update the handbook, we estimate a one-time private sector burden of 400 hr (100 entities × 4 hr)

and $21,328 (400 hr × $53.32/hr). To send the handbook to existing enrollees in the 100 entities, we estimate a one-time private sector burden of 177,699 hr (10,659,819 enrollees × 1 min) and $4,691,258.42 (177,699 hr × $26.40/hr).

With regard to new enrollees, they must receive a handbook within a reasonable time after receiving notice of the beneficiary's enrollment. We assume a 3.3 percent enrollee growth rate thus 2,069,259 enrollees (5 percent of 62,704,821) would need to receive a handbook each year. We estimate 1 min by a mail clerk at $26.40/hr to mail the handbook or 34,488 hr (2,069,259 enrollees × 1 min). The currently approved burden estimates 5 min per mailing for 390,000 enrollees or 32,500 total hr. Updating the enrollment figure and reducing the time from 5 min to 1 min (to acknowledge current automated mailing processes), the annual private sector burden is increased by 1,988 hr (34,488 hr − 32,500 hr) and $52,483.20 (1,988 hr × $26.40/hr).

Since all of the MCO, PIHP, PAHP, and PCCM entities would need to keep their handbook up to date, we estimate it would take 1 hr at $53.32/hr for a business operations specialist to update the document. While the updates would be necessary when program changes occur, we estimate 1 hr since each change may only take a few minutes to make. In aggregate, we estimate an annual private sector burden of 577 hr (577 entities × 1 hr) and $30,765.64 (577 hr × $53.32/hr).

Section 438.10(h) would require that all MCO, PIHP, PAHP, and PCCM entities make a provider directory available in paper or electronic form. Producing a provider directory is a longstanding requirement in § 438.10 and in the commercial health insurance market. Given the time sensitive nature of provider information and the high error rate in printed directories, most provider information is now obtained via the internet or by calling a customer service representative. In this regard, the only new burden is the time a computer programmer would need to add a few additional fields of data, including the provider Web site addresses, additional disability accommodations, and adding behavioral and long-term services and support providers.

We estimate that it would take approximately 1 hr at $73.60/hr for a computer programmer to update the existing directory. Updates after the creation of the original program would be put on a production schedule as part of usual business operations and would not generate any additional burden. In aggregate, we estimate a one-time private sector burden of 577 hr (577 entities × 1 hr) and $42,467.20 (577 hr × $73.60/hr).

8. ICRs Regarding Requirements That Apply to MCO, PIHP, PAHP, and PCCM Contracts Involving Indians, Indian Health Care Providers, and Indian Managed Care Entities (§ 438.14)

Section 438.14(c) would require states to make supplemental payments to Indian providers if the MCO, PIHP, PAHP, and PCCM entity does not pay at least the amount paid to Indian providers under the FFS program. There are approximately 31 states with 463 managed care entities with Indian providers. This type of payment arrangement typically involves the managed care entity sending a report to the state that then calculates and pays the amount owed to the Indian health care provider.

We estimate it would take 1 hr at $73.60/hr for a private sector computer programmer to create the claims report and approximately 12 hr at $53.32/hr for a state business operations specialist to process the payments. We estimate that approximately 25 of the 31 states will need to use this type of arrangement. In aggregate, we estimate a one-time private sector burden of 463 hr (463 entities × 1 hr) and $34,076.80 (463 hr × $73.60/hr). We also estimate an annual state burden of 300 hr (25 states × 12 hr) and $15,996 (300 hr × $53.32/hr).

After the MCO, PIHP, PAHP, and PCCM report is created, it will most likely run automatically at designated times and sent electronically to the state as the normal course of business operations; therefore, no additional private sector burden is estimated after the first year. (Note: This process is not necessary when the MCO, PIHP, PAHP, or PCCM entity pays the ICHP at least the full amount owed under this regulation.)

9. ICRs Regarding Managed Care Enrollment (§ 438.54)

Section 438.54(c)(2) would require states with voluntary programs that use a passive enrollment process to provide a 14-day choice period before enrolling the potential enrollee into a managed care plan. (Currently, such states enroll the potential enrollee into a managed care plan on the first day of their eligibility.) We estimate approximately 21 states have voluntary programs and approximately 75 percent of them (15) use a passive process. To accommodate the 14-day choice period, these 15 states would have to alter the programming of their passive enrollment algorithm to delay the enrollment in a managed care plan until the enrollee makes a plan selection or the 14-day period expires. We estimate it would take a computer programmer 2 hours at $73.60/hr to complete this change. In aggregate, we estimate a one-time state burden of 30 hours (15 states × 2 hr) and $2,208 (30 hours × $73.60).

Section 438.54(c)(3) and (d)(3) would require states to notify the potential enrollee of the implications of not making an active choice during the allotted choice period. This information should be included in the notice of eligibility determination (or annual redetermination) required under § 445.912, thus no additional burden is estimated here.

Section 438.54(c)(8) would require states to send a notice to enrollees in voluntary programs that utilize a passive enrollment process confirming their managed care enrollment when they have the opportunity to select a delivery system. We believe that by implementing the 14-day choice period, some states currently using passive enrollment process will discontinue its use. Therefore, we assume only 10 states will continue using a passive enrollment process, with a total of 14,929,719 enrollees. Assuming a 5 percent of these would be new each year, and of those, that approximately 75 percent will elect managed care (559,865) we estimate 1 min per notification by a mail clerk at $26.40/hr. In aggregate, we estimate an annual state burden of 9,350 hours (559,865 enrollees × 1 min) and $246,833.28 (9,350 hr × $26.40/hr).

10. ICRs Regarding Continued Services to Beneficiaries (§ 438.62)

Section 438.62(b)(1) would require states to have a transition of care policy for all beneficiaries moving from FFS Medicaid into a MCO, PIHP, PAHP or PCCM, or when an enrollee is moving from one MCO, PIHP, PAHP, or PCCM to another and that enrollee would experience a serious detriment to health or be at risk of hospitalization or institutionalization without continued access to services. As states are currently required to ensure services for enrollees during plan transitions, they have a policy but it may need to be revised to accommodate the proposed requirements and to include transitions from FFS. We estimate it would take a business operations specialist 5 hours at $53.32/hr to revise their policies and procedures and 4 hr at $73.60/hr for a computer programmer to create a program to compile and send the data. In aggregate, we estimate a one-time state burden of 378 hr (42 states × 9 hr) and $23,562.00 (210 hr × $53.32/hr + 168 hr × $73.60/hr). We are not

estimating additional burden for the routine running of these reports since they will be put into a production schedule.

Section 438.62(b)(2) would require that MCOs, PIHPs, PAHPs, and PCCMs implement their own transition of care policy that meets the requirements of § 438.62(b)(1). Under current requirements and as part of usual and customary business practice for all managed care plans, the MCOs, PIHPs, PAHPs, or PCCMs already exchange data with each other for this purpose. To revise their existing policies to reflect the standards in (b)(1), we estimate 1 hr at $53.32 for a business operations specialist. To develop computer programs to receive and store FFS data, we estimate 4 hr at $73.60/hr for a computer programmer. We are not estimating additional burden for the routine running of these reports since they will be put into a production schedule. In aggregate, we estimate a one-time private sector burden of 568 hr (568 MCOs, PIHPs, PAHPs, and PCCMs × 1 hr) and $30,285.76 (568 hr × $53.32/hr) and 2,272 hr (568 × 4 hr) and $167,219 (2,272 hr × $73.60/hr).

For transitions, we estimate 10 min (per request) at $65.40/hr for a registered nurse to access the stored data and take appropriate action. We also estimate that approximately 0.05 percent of enrollees (313,704) may meet the state defined criteria for serious detriment to health and/or risk of hospitalization or institutionalization. In aggregate, we estimate an annual private sector burden of 52,294 hr (313,704 enrollees × 10 min) and $3,420,057.47 (52,294 hr × $65.40/hr).

11. ICRs Regarding State Monitoring Procedures (§ 438.66)

Section 438.66(a) and (b) would require states with MCO, PIHP, PAHP, or PCCM programs to have a monitoring system including at least the 13 areas specified in paragraph (b). While having a monitoring system is a usual and customary business process for all of the state Medicaid agencies, including all 13 areas will require most states to make at least some revisions to their existing processes and policies. We estimate 8 hr at $53.32/hr for a business operations specialist to expand or revise existing policies and procedures. In aggregate, we estimate a one-time state burden of 336 hr (42 states × 8 hr) and $17,915.52 (336 hr × $53.32/hr).

Section 438.66(c) would require states with MCO, PIHP, PAHP, or PCCM programs to utilize data gathered from its monitoring activities in 12 required areas to improve the program's performance. While all states currently utilize data for program improvement to some degree, incorporating all 12 areas will likely require some revisions to existing policies and procedures. We estimate a one-time state burden of 20 hr at $53.32/hr for a business operations specialist to revise existing or to create new policies and procedures for utilizing the collected data. In aggregate, we estimate 840 hr (42 states × 20 hr) and $44,788.80 (840 hr × $53.32/hr).

Section 438.66(d)(1) through (3) would require that states include a desk review of documents and an on-site review for all readiness reviews when certain events occur. For preparation and execution of the readiness review, we estimate 5 hr (at $127.72/hr) for a general and operations manager, 30 hr (at $53.32/hr) for a business operations specialist, and 5 hr (at $73.60/hr) for a computer programmer. The time and staff types are estimated for a new program or new entity review and may vary downward when the review is triggered by one of the other events listed in (d)(1). Given the varying likelihood of the 5 events listed in (d)(1), we will use an average estimate of 20 states per year having one of the triggering events. In aggregate, we estimate an annual state burden of 800 hr (20 states × 40 hr) and $52,124 [20 states × ((5 × $127.72/hr) + (30 × $53.32/hr) + (5 × $73.60/hr))].

For MCO, PIHP, PAHP, or PCCM preparation and execution, we estimate 5 hr (at $127.72/hr) for a general and operations manager, 30 hr (at $53.32/hr) for a business operations specialist, and 5 hr (at $73.60/hr) for a computer programmer. In aggregate, we estimate an annual private sector burden of 800 hr (20 entities × 40 hr) and $52,124 [20 entities × ((5 × $127.72/hr) + (30 × $53.32/hr) + (5 × $73.60/hr))].

Section 438.66(e)(1) and (2) would require that states submit an annual program assessment report to CMS covering the topics listed in § 438.66(e)(2). The data collected for § 438.66(b) and the utilization of the data in § 438.66(c) will be used to compile this report. We estimate an annual state burden of 6 hr at $53.32/hr for a business operations specialist to compile and submit this report to CMS. In aggregate, we estimate an annual state burden of 252 hr (42 states × 6 hr) and $13,436.64 (252 hr × $53.32/hr).

12. ICRs Regarding Network Adequacy (§ 438.68)

Section 438.68(a) would require that states set network adequacy standards that each MCO, PIHP and PAHP must follow. Section 438.68(b) and (c) would require that states set standards which must include time and distance standards for specific provider types and must develop network standards for LTSS if the MCO, PIHP or PAHP has those benefits covered through their contract.

We estimate states would spend 10 hr in the first year to develop the network adequacy standards for the specific provider types found in § 438.68(b)(1). While 40 states have contracted with at least one MCO, PIHP or PAHP, we believe that 20 will need to develop the standards. After the network standards have been established, we estimate that the maintenance of the network standards will occur only periodically as needs dictate; therefore, we do not estimate additional burden for states after the first year.

To develop network standards meeting the specific provider types found in § 438.68(b)(1), we estimate a one-time state burden of 10 hr at $53.32/hr for a business operations specialist. In aggregate, we estimate 200 hr (20 states × 10 hr) and $10,664 (200 hr × $53.32/hr).

To develop LTSS standards, we estimate a one-time state burden of 10 additional hr at $53.32/hr for a business operations specialist to develop those standards. In aggregate, we estimate 160 hr (16 states with MLTSS programs × 10 hr) and $8,531.20 (160 hr × $53.32/hr).

Section 438.68(d) would require the state to develop an exceptions process for use by MCOs, PIHPs, and PAHPs unable to meet the network standards established in § 438.68(a). We estimate a one-time state burden of 3 hr at $53.32/hr for a business operations specialist to design an exceptions process for states to use to evaluate requests from MCOs, PIHP, and PAHPs for exceptions to the network standards. With a total of 40 states contracting with at least one MCO, PIHP or PAHP, we estimate a one-time aggregate state burden of 120 hr (40 states × 3 hr) and $6,398.40 (120 hr × $53.32).

The exception process should not be used very often as MCOs, PIHPs, and PAHPs meeting the established standards is critical to enrollee access to care. As such, after the exceptions process is established, we estimate that the occasional use of it will not generate any measurable burden after the first year.

States' review and reporting on exceptions granted through the process developed in § 438.68(d) is estimated under § 438.66 so we do not estimate any additional burden for this requirement.

13. ICRs Regarding Stakeholder Engagement When LTSS Is Delivered Through a Managed Care Program (§ 438.70)

Section 438.70(c) would require that states continue to solicit and address public input for oversight purposes. Existing MLTSS programs already meet this requirement and we estimate no more than 14 new programs.

We estimate an annual state burden of 4 hr at $53.32/hr for a business operations specialist to perform this task. In aggregate, we estimate 56 hr (14 states × 4 hr) and $2,985.92 (152 hr × $53.32/hr).

14. ICRs Regarding Beneficiary Support System (§ 438.71)

Section 438.71(a) would require the state to develop and implement a system for support to beneficiaries before and after enrollment in a MCO, PIHP, PAHP, or PCCM. This will most likely be accomplished via a call center including staff having email capability—internal to the state or subcontracted—that will assist beneficiaries with questions. As most state Medicaid programs already provide this service, we estimate only 20 states may need to take action to address this requirement.

We estimate a state would need 150 hr to either procure a vendor for this function or create an internal call center. The one-time state burden would consist of 125 hr (at $53.32/hr) for a business operations specialist, and 25 hr (at $127.72/hr) for a general and operations manager. In aggregate, we estimate 3,000 hr (20 states × 150 hr) and $197,160 [20 states × ((125 hr × $53.32/hr) + (25 hr × $127.72/hr))].

Section 438.71(b) would require the system to include choice counseling for enrollees, training for providers, outreach for enrollees, and education and problem resolution for services, coverage, and access to LTSS. This system must be accessible in multiple ways including at a minimum, by telephone and email. Some in-person assistance may need to be provided in certain circumstances. Most states will likely use the call center created in § 438.71(a) to handle the majority of these responsibilities and use existing community-based outreach/education and ombudsman staff, whether state employees or contractors, for the occasional in person request. The use of existing staff will add no additional burden as it is part of standard operating costs for operating a Medicaid program.

The provider training will likely involve developing materials thus we are estimating 3 hr at $53.32/hr for a business operations specialist to create materials specifically for provider education on MLTSS and 1 hr to update those materials (given the fluid nature of community resources). As almost all materials for providers are sent electronically, we estimate only the additional time needed to produce the materials here. In aggregate, we estimate a one-time state burden of 126 hr (42 states × 3 hr) and $6,718.32 (126 hr × $53.32/hr). We also estimate an annual state burden of 42 hr (42 states × 1 hr) and $2,239.44 (42 hr × $53.32/hr).

15. ICRs Regarding Member Advisory Committee (§ 438.110)

Section 438.110(a) would require each MCO, PIHP, and PAHP to establish and maintain a member advisory board if the LTSS population is covered under the contract. We estimate an annual private sector burden of 6 hr at $53.32/hr for a business operations specialist to maintain the operation of the committee (hold meetings, distribute materials to members, and maintain minutes) for up to 14 new programs. Existing programs already meet this requirement. In aggregate, we estimate 84 hr (14 states × 6 hr) and $4,478.88 (84 hr × $53.32/hr).

16. ICRs Regarding Assurances of Adequate Capacity and Services (§ 438.207)

Section 438.207(c) would add a requirement that the documentation required in § 438.207(b) be submitted to the state at least annually. As the MCOs, PIHPs, and PAHPs would already run and review these reports periodically to monitor their networks as part of normal network management functions and as part of the provisions of § 438.68, the only additional burden would possibly be (if the state doesn't already require this at least annually) for the MCOs, PIHPs, and PAHPs to revise their policy to reflect an annual submission. We estimate a one-time private sector burden of 1 hr at $53.32/hr for a business operations specialist to revise the policy, if needed. In aggregate, we estimate 568 hr (568 entities × 1 hr) and $30,285.76 (568 hr × $53.32/hr). We also estimate an annual private sector burden of 2 hr to compile and submit the information necessary to meet the requirements § 438.207(b) through (d). In aggregate, we estimate 1,136 hr (568 entities × 2 hr) and $60,571.52 (1,136 hr × $53.32/hr).

17. ICRs Regarding Coordination and Continuity of Care (§ 438.208)

Section 438.208(b)(2)(iii) would require that MCOs, PIHPs and PAHPs coordinate service delivery with the services the enrollee receives in the FFS program (carved out services). This involves using data from the state to perform the needed coordination activities. The exchange of data and the reports needed to perform the coordination activity is addressed in the requirements in § 438.62(b)(2). Since only a small percentage of enrollees receive carved out services and need assistance with coordination, we estimate 5 percent of all MCO, PIHP, and PAHP enrollees (2,746,476) will be affected. We estimate an ongoing private sector burden of 10 min (per enrollee) at $59.20/hr for a healthcare social worker to perform the care coordination activities. In aggregate, we estimate 457,746 hr (2,746,476 enrollees × 10 min) and $27,099,105.17 (457,746 hr × $59.20/hr).

Section 438.208(b)(3) would require that a MCO, PIHP or PAHP make its best effort to conduct an initial assessment of each new enrollee's needs within 90 days of the enrollment. We believe that most MCOs and PIHPs already meet this requirement and only 25 percent of the MCOs and PIHPs (127) will need to alter their processes; however, we do not believe this to be as common a practice among PAHPs and assume that all 41 PAHPs will be need to add this assessment to their initial enrollment functions. We estimate a one-time private sector burden of 3 hr at $53.32/hr for a business operations specialist to revise their policies and procedures. In aggregate, we estimate 504 hr [(127 MCOs/PIHPs + 41 PAHPs) × 3 hr] and $26,873.28 (504 hr × $53.32/hr).

We estimate that in a given year, only 5 percent (485,872) of 25 percent of MCO and PIHP and all PAHP enrollees are new to a managed care plan. We estimate an annual private sector burden of 10 min (on average) at $29.68/hr for a customer service representative to complete the assessment. In aggregate, we estimate 80,980 hr (485,872 enrollees × 10 min) and $2,403,494.90 (80,980 hr × $29.68/hr).

Section 438.208(b)(4) would require that MCOs, PIHPs, and PAHPs share with other MCOs, PIHPs, and PAHPs serving the enrollee the results of its identification and assessment of any enrollee with special health care needs so that those activities need not be duplicated. The burden associated with this requirement is the time it takes each MCO, PIHP or PAHP to disclose information on new enrollees to the MCO, PIHP or PAHP providing a carved out service. This would most likely be accomplished by developing a report to collect the data and posting the completed report for the other MCO, PIHP, or PAHP to retrieve.

We estimate a one-time burden of 4 hr at $73.60/hr for a computer programmer to develop the report. In aggregate, we estimate 2,272 hr (568 MCOs, PIHPs, and PAHPs × 4 hr) and $167,219 (2,272 hr × $73.60/hr). However, while the currently approved burden sets out 45 min per enrollee and 464,782 annual hours, to provide more accurate estimates we are adjusting the burden by using one-time per plan estimates and recognizing the use of automated reporting. In aggregate, we estimate a one-time private sector burden of −462,510 hr (2,272 hr −464,782 hr) and −$34,040,736 (−462,510 hr × $73.60/hr). Once put on a production schedule, no additional staff time would be needed, thus no additional burden is estimated.

Section 438.208(c)(2) and (3) currently require that MCOs, PIHPs and PAHPs complete an assessment and treatment plan for all enrollees that have special health care needs; we propose to add ''enrollees who require LTSS'' to this section. These assessments and treatment plans should be performed by providers or MCO, PIHP or PAHP staff that meet the qualifications required by the state. We believe the burden associated with this requirement is the time it takes to gather the information during the assessment. (Treatment plans are generally developed while the assessment occurs so we are not estimating any additional time beyond the time of the assessment.) We believe that only enrollees in MCOs and PIHPs will require this level of assessment as most PAHPs provide limited benefit packages that do not typically warrant a separate treatment plan.

While this is an existing requirement, we estimate an additional 1 percent of the total enrollment of 42,812,879 (428,128) given the surge in enrollment into managed care of enrollees utilizing LTSS. We estimate an annual private sector burden of 1 hr (on average) at $65.40/hr for a registered nurse to complete the assessment and treatment planning. In aggregate, we estimate an additional 428,128 hr (428,128 enrollees × 1 hr) and $27,999,571 (428,128 hr × $65.40/hr).

Section 438.208(c)(3)(v) would add a requirement that treatment plans be updated at least annually or upon request. We estimate a one-time private sector burden of 1 hr at $53.32/hr for a business operations specialist to revise policies and procedures to reflect a compliant time frame. In aggregate, we estimate 568 hr (568 MCOs, PIHPs, PAHPs × 1 hr) and $30,285.76 (568 hr × $53.32/hr).

18. ICRs Regarding Coverage and Authorization of Services (§ 438.210)

Section 438.210(a)(4)(ii)(B) would require that MCOs, PIHPs, and PAHPs authorize services for enrollees with chronic conditions or receiving LTSS in a way that reflects the on-going nature of the service. While we expect this to already be occurring, we would expect that most MCOs, PIHPs, and PAHPs would review their policies and procedures to ensure compliance. We estimate a one-time private sector burden of 20 hr at $65.40/hr for a registered nurse to review and revise, if necessary, authorization policies and procedures. In aggregate, we estimate 11,360 hr (568 MCOs, PIHPs, and PAHPs × 20 hr) and $742,944 (11,360 × $65.40/hr)

Section 438.210(c) currently requires that each contract provide for the MCO or PIHP to notify the requesting provider, and give the enrollee written notice of any decision by the MCO, PIHP, or PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. In this proposed rule, PAHPs would be added to this requirement.

The burden associated with sending adverse benefit determination notices is included in § 438.404. While we believe PAHPs already provide notification of denials, we expect they may need to be revised to be compliant with § 438.404. We estimate a one-time public sector burden of 1 hr at $53.32/hr for a business operations specialist to revise the template. In aggregate, we estimate 61 hr (61 PAHPs × 1 hr) and $3,252.52 (61 hr × $53.32/hr).

19. ICRs Regarding Subcontractual Relationships and Delegation (§ 438.230)

Section 438.230 would require additional provisions in MCO, PIHP, or PAHP subcontracts, other than agreements with network providers. We estimate a one-time private sector burden of 3 hr at $53.32/hr for a business operations analyst to amend appropriate contracts. In aggregate, we estimate 1,704 hr (568 MCO, PIHP, or PAHP × 3 hr) and $90,857.28 (1,704 × $53.32/hr).

20. ICRs Regarding Health Information Systems (§ 438.242)

Section 438.242(b) and (c) currently requires MCOs and PIHPs to collect and submit to the state enrollee encounter data. We propose to add PAHPs to the requirement. We estimate a one-time private sector burden of 20 hr at $73.60/hr for a computer programmer to extract this data from a PAHP's system and report it to the state. In aggregate, we estimate 820 hr (41 entities × 20 hr) and $60,352 (820 hr × $73.60/hr). After creation, these reports would be set to run and sent to the state at on a production schedule.

21. ICRs Regarding Basis, Scope, and Applicability (§ 438.310)

Section 438.310(c)(2) is new and would have states assess the performance of each PCCM entity described in § 438.3(r). Section 438.3(r) describes a specific subset of PCCM entities; therefore we estimate that this change will affect 10 states, or approximately 15 PCCM entities. At a minimum, the assessment would include the elements in § 438.330(b)(3), (c), and (e).

We estimate a one-time state burden of 2 hr at $53.32/hr for a business operations specialist to address the performance assessment of PCCM entities specified at § 438.3(r) by revising a state's policies and procedures. In aggregate, we estimate 20 hr (10 states × 2 hr) and $1,066.40 (20 hr × $53.32/hr).

22. ICRs Regarding Quality Assessment and Performance Improvement Program (§ 438.330, Formerly § 438.240)

Section 438.330(a)(2) alters the process we would use to specify performance measures and PIP topics to include a public notice and comment process. Assuming that we do use this process to identify performance measures and PIP topics at least once every 3 years, the burden for states will be altered. Some may experience a decrease in the time spent selecting performance measures and PIP topics while others might experience a slight increase in the form of programming their MMIS systems to account for the specified performance measures and PIP topics.

We estimate an annual state burden of 10 hr (every 3 years) at $73.60/hr for a computer programmer to make the MMIS programming changes. In aggregate, we estimate an annualized burden of 133.3 hr [(40 states × 10 hr)/ 3 years] and $9,810.88 (133.3 hr × $73.60/hr). We cannot estimate the amount of possible decrease in burden as we have no way to know the average amount of time a state expended on selecting performance measures or PIP topics and how this might change based on this revision.

Section 438.330(a)(2)(i) would allow states to select performance measures and performance improvement projects (PIPs) in addition to those specified by CMS under § 438.330(a)(2). Since this

language continues the flexibility available to states today, we do not believe this creates any change in burden for states or the private sector.

Section 438.330(a)(2)(ii) would allow states to apply for an exemption from the CMS-specified performance measures and PIP topics established under § 438.330(a)(2). While we have no data on how many states would take advantage of this option, given that the performance measures and PIP topics under § 438.330(a)(2) would be identified through a public notice and comment process, we estimate that 25 percent of states (11 states) would ask for an exemption every 3 years. We estimate an annual state burden of 1 hr at $53.32/hr for a business operations specialist to comply with the exemption process. In aggregate, we estimate an annualized burden of 3.7 hr [(11 states × 1 hr)/3 years] and $197.28 (3.7 hr × $53.32/hr).

Section 438.330(b)(3) clarifies that MCOs, PIHPs, and PAHPs would have an approach to evaluate and address findings regarding the underutilization and overutilization of services. Because utilization review in managed care has become commonplace in the commercial, Medicare, and Medicaid settings, we do not believe that this regulatory provision imposes any new burden on MCOs, PIHPs, or PAHPs. However, in accordance with § 438.310(c)(2), some PCCM entities (we estimate 15) would now be subject to this operational component.

We recognize that PCCM entities may not currently have in place mechanisms to assess and address underutilization and overutilization of services in accordance with § 438.330(b)(3). We estimate a one-time private sector burden of 10 hr at $53.32/hr for a business operations specialist to establish the policies and procedures. In aggregate, we estimate 150 hr (15 PCCM entities × 10 hr) and $7,998 (150 hr × $53.32/hr) for program establishment. We also estimate an annual burden of 10 hr to evaluate and address the findings. In aggregate, we estimate 150 hr (15 PCCM entities × 10 hr) and $7,998 (150 hr × $53.32/hr) for program maintenance.

Section 438.330(c)(1) through (3) would include conforming changes, specifically the addition of PAHPs to the list of affected managed care entities and updated citations. The section states that each MCO and PIHP annually measures its performance using standard measures specified by the state and report its performance to the state. We assume that each of the 335 MCOs and 176 PIHPs would report on three performance measures to the state. The use of performance measures is commonplace in commercial, Medicare, and Medicaid managed care markets; therefore we believe that MCOs and PIHPs already collect performance measures.

For MCOs (335) and PIHPs (176), we estimate an annual private sector burden of 0.1 hr at $53.32/hr for a business operations specialist to report on a single performance measure to the state. In aggregate, we estimate 153.3 hr (511 MCOs and PIHPs × 3 performance measures × 0.1 hr) and $8,173.96 (153.3 hr × $53.32/hr).

In accordance with § 438.310(c)(2), some PCCM entities would now be subject to the performance measurement standards under § 438.330(c). We recognize that PAHPs and PCCM entities may not currently engage in performance measurement as described in § 438.330(c). We estimate that each PCCM entity and each PAHP would report to the state on 3 performance measures annually. For the 15 PCCM entities and 41 PAHPs, we estimate an annual private sector burden of 4 hr (per measure) at $53.32/hr for a business operations specialist to collect, calculate, and submit each performance measure to the state. In aggregate, we estimate 672 hr (56 PAHPs and PCCMs × 3 performance measures × 4 hr) and $35,831.04 (672 hr × $53.32/hr).

In § 438.330(c)(4) we propose that, in addition to the performance measures otherwise specified under § 438.330(c)(1) through (3), MCOs, PIHPs, and PAHPs that provide LTSS services would collect and report on two categories of measures specific to LTSS. Assuming that each of the 179 MLTSS plans reports on at least one measure per category and a burden of 4 hr (per measure) at $53.32/hr for a business operations specialist to collect, calculate, and submit each LTSS performance measure to the state, we estimate an aggregated private sector burden of 1,432 hr (179 MLTSS plans × 2 performance measures × 4 hr) and $76,354.24 (1,432 hr × $53.32/hr).

Section 438.330(d)(1) would have states ensure that each MCO and PIHP has an ongoing program of PIPs. In § 438.330(d)(2), each MCO and PIHP would report the status and results of each such PIP to the state as requested. For the standards for ongoing PIPs in § 438.240(d), we estimate that each MCO and PIHP would conduct at least 3 PIPs in any given year. We further expect that states would request the status and results of each entity's PIPs annually. The currently approved burden under this control number estimates that each of 539 MCOs and PIHPs conducts 3 PIPs, for a burden of 12,936 hr (539 MCOs and PIHPs × 3 PIPs × 8 hr). However, this figure overestimates the number of MCOs and PIHPs. Therefore, we estimate an annual private sector burden of 8 hr at $53.32/hr for a business operations specialist to report on each PIP. In aggregate, we estimate 12,264 hr (511 MCOs and PIHPs × 8 hr × 3 PIPs) and $653,916.48 (12,264 hr × $53.32/hr).

Section 438.330(d)(1) and (2) would add PAHPs to the list of affected managed care entities. While we recognize that PAHPs may not currently be conducting PIPs, we assume that each PAHP would conduct at least one PIP each year. We expect that states would request the status and results of each PAHP's PIP annually. We estimate a one-time private sector burden of 2 hr at $53.32/hr for a business operations specialist to develop policies and procedures. In aggregate, we estimate 82 hr (41 PAHPs × 2 hr) and $4,372.24 (82 hr × $53.32/hr). We also estimate an annual private sector burden of 8 hr to prepare a PIP report. In aggregate, we estimate 328 hr (41 PAHPs × 1 PIP × 8 hr) and $17,488.96 (328 hr × $53.32/hr).

Per § 438.310(c)(2), PCCM entities specified at § 438.3(r) would also be subject to the program components in § 438.330(e). We estimate an annual state burden of 15 hr at $53.32/hr for a business operations specialist to assess the performance of a single § 438.3(r) PCCM entity. In aggregate, we estimate 225 hours (15 PCCM entities × 15 hr) and $11,997 (225 hr × $53.32/hr).

Under section 438.330(e)(1)(ii), states would include outcomes and trended results of each MCO, PIHP, and PAHP's PIPs in the state's annual review of quality assessment and performance improvement programs. We estimate a one-time state burden of 0.5 hr at $53.32/hr for a business operations specialist to modify policies and procedures for the 40 states with MCOs, PIHPs and PAHPs. In aggregate, we estimate 20 hr (40 states × 0.5 hr) and $1,066.40 (20 hr × $53.32/hr). We also estimate an annual state burden of 1 hr to conduct the additional annual review of the outcomes and trended results for MCOs, PIHPs, and PAHPs. In aggregate, we estimate 40 hr (40 states × 1 hr) and $2,132.80 (40 hr × $53.32/hr).

Section 438.330(e)(1)(iii) is a new program component, related to § 438.330(b)(5), which would have a state (in its annual review) assess the results of any efforts to support state goals to promote community integration of beneficiaries using LTSS in place at the MCO, PIHP, or PAHP. We estimate that the 16 states with MLTSS plans would need to modify their policies and procedures regarding the annual review

of quality assessment and performance improvement programs in their managed care entities. We estimate a one-time state burden of 0.5 hr at $53.32/hr for a business operations specialist to modify the state's policies and procedures. In aggregate, we estimate 8 hr (16 states × 0.5 hr) and $426.56 (8 hr × $53.32/hr). We also estimate an annual burden of 1 hr for the assessment of rebalancing efforts. In aggregate, we estimate 16 hr (16 states × 1 hr) and $853.12 (16 hr × $53.32/hr) for the assessment.

23. ICRs Regarding State Review and Approval of MCOs, PIHPs, and PAHPs (§ 438.332)

Under this new section, states would review and approve MCO, PIHP, and PAHP performance, at least once every 3 years, in accordance with standards at least as strict as those used by a private accrediting entity that is approved or recognized by CMS under the existing Marketplace and MA programs, as a condition of contracting with the state. It would also grant states the option of allowing MCOs, PIHPs, and PAHPs to meet this standard by presenting proof of accreditation by a private accrediting entity recognized by CMS. MCOs, PIHPs, and PAHPs would maintain state approval for the duration of participation in the Medicaid program. State approval of MCOs, PIHPs, and PAHPs would be renewed every 3 years.

A number of states already either include accreditation by a private accrediting entity as a component of their managed care contracting process or recognize such accreditation. We estimate that half of states (20 states) would elect to establish their own state review and approval process (per § 438.332(a)) and the remainder (20 states) will elect to use the accreditation deeming option (per § 438.332(b)). We further estimate that half (276) of the total number of MCOs, PIHPs, and PAHPs (552) will be subject to each process.

Section 438.332(a) would establish that to enter into a contract with the state, the performance of each MCO, PIHP, and PAHP would be reviewed and approved by the state, using a set of standards that are at least as stringent as those used by a private accrediting entity recognized by CMS either for MA or Qualified Health Plan accreditation. It would also define maintenance of state approval as a condition of its contract. While we are aware of at least one state that operates its own accreditation process, we do not have any data regarding the costs of this type of review and approval system and thus estimate all burdens associated with this process.

We expect that states would have to purchase the accreditation standards of a private accrediting entity recognized by CMS to determine if its standards for MCOs, PIHPs, and PAHPs are at least as stringent as those used by a private accrediting entity. We estimate that this would cost $20,000 per state, and that states would have to purchase these standards at least once every 3 years. In aggregate, we estimate an ongoing annualized state burden of $133,333.33 [(20 states × $20,000)/3 years] for the purchase of the accreditation standards of a private accrediting entity.

After purchasing these standards, the state would use them to develop its own standards which are at least as stringent as those used by the private accrediting entity. We estimate that states would conduct this process at least once every 3 years. We estimate an annual state burden of 15 hr at $53.32/hr for a business operations specialist and 5 hr at $127.72/hr for a general and operations manager. In aggregate, we estimate an annualized burden of 133.3 hr [(20 states × 20 hr)/3 years] and $9,589.33 [((20 states × 15 hr × $53.32/hr) + (20 states × 5 hr × $127.72/hr))/3 years].

The state would then use its standards to review and approve the performance of each plan at least once every 3 years. For plan review and approval, we estimate an annual state burden of 80 hr at $53.32/hr for a business operations specialist, 5 hr at $127.72/hr for a general and operations manager, and 5 hr at $29.92/hr for an office and administrative support worker. In aggregate, we estimate an annualized state burden of 8,280 hr (276 MCOs, PIHPs, and PAHPs × 90 hr/3 years) and $464,949.60 [(276 MCOs/PIHPs/PAHPs × [(80 hr × $53.32/hr) + (5 hr × $127.72/hr) + (5 hr × $29.92/hr)])/3 years] to review and approve MCOs, PIHPs, and PAHPs.

For the state to review and approve a plan, the MCO, PIHP, or PAHP would have to provide certain information to the state. As a condition of contracting with the states, plans would have to maintain state approval (a process which we estimate will occur at least once every 3 years); therefore plans would provide this information to the state at least once every 3 years. We estimate a burden of 40 hr at $53.32/hr for a business operations specialist, 5 hr at $29.92/hr for an office and administrative support worker, and 4 hr at $127.72/hr for a general and operations manager to compile and provide this information. In aggregate we estimate an annualized private sector burden of 4,508 hr [(276 MCOs, PIHPs, and PAHPs × 49 hr/3 years) and $256,981.76 [(276 MCOs, PIHPs, and PAHPs × [(40 hr × $53.32/hr) + (5 hr × $29.92/hr) + (4 hr × $127.72/hr)])/3 years].

Section 438.332(b) would allow states to deem compliance with the process in § 438.332(a) for MCOs, PIHPs, and PAHPs that provide proof and documentation of accreditation by a private accrediting entity recognized by CMS. We estimate the burden for the operation of the state deeming process as 40 hr at $53.32/hr for a business operations specialist to oversee and collect private accreditation information from MCOs, PIHPs, and PAHPs. In aggregate, we estimate an annualized state burden of 266.7 hr [(20 states × 40 hr)/3 years] and $14,220.44 (266.7 hr × $53.32/hr) for the oversight and operation of the accreditation deeming process.

Under § 438.332(b)(2), MCOs, PIHPs, and PAHPs would authorize the private accrediting entity to release accreditation information to the state to deem compliance with § 438.332(a). We believe that an indeterminate number (estimated to be half, or 138 MCOs, PIHPs, and PAHPs) of these entities may already have received or are independently seeking accreditation, and thus would not face any additional burden associated with this section.

The remaining 138 MCOs, PIHPs, and PAHPs would have to seek initial accreditation from a private accrediting entity. The burden for accreditation varies widely, depending on a number of factors including the type of managed care entity, the size of its population, and the accrediting body. We estimate that initial accreditation costs $70,700 per plan (given that private accrediting entities structure prices in terms of accreditation activities, not hours, an hourly burden estimate is not available) and would be renewed once every 3 years for the same cost. In aggregate, we estimate the one-time private sector burden for initial accreditation is $9,756,600 (138 MCOs, PIHPs, and PAHPs × $70,700) and an annualized private sector burden of $3,252,200 [(138 MCOs, PIHPs, and PAHPs × $70,700)/3 years] for accreditation renewal.

Section 438.332(c) would have the state document its determinations for all MCOs, PIHPs, and PAHPs on the state's Web site. The burden is included in § 438.10.

24. ICRs Regarding Medicaid Managed Care Quality Rating System (§ 438.334)

Section 438.334 (a) would have each state which contracts with an MCO,

PIHP or PAHP establish a quality rating system to generate plan ratings. These quality ratings would: (1) Be based on the three specified components (clinical quality management, member experience, and plan efficiency, affordability, and management), (2) use outcomes data from the CMS-specified performance measures in 438.330(a)(3), and (3) be prominently displayed by the state on its Web site.

We assume each state would create a single quality rating system for all its MCOs, PIHPs, and PAHPs. Section 438.334(c) would provide states with the option to use their own quality rating system in place of the system proposed under this section; therefore, we estimate that 30 states would have to create quality rating systems. We further estimate that 75 percent (414) of MCOs, PIHPs, and PAHPs operate in these 30 states. We also assume that each state would utilize a public engagement process to solicit feedback on its quality rating system.

We estimate the burden for the development of a state quality rating system as 100 hr at $53.32/hr for a business operations specialist, 40 hr at $73.60/hr for a computer programmer, and 15 hr at $127.72/hr for a general and operations manager. We estimate an additional 2 hr at $29.92/hr for an office and administrative support worker for the public engagement process and an additional 15 hr at $53.32/hr for a business operations specialist to review and incorporate public feedback. In aggregate, we estimate a one-time state burden of 5,160 hr (30 states × 172 hr) and $331,543.20 [30 states × ((100 hr × $53.32/hr) + (40 hr × $73.60/hr) + (15 hr × $127.72/hr) + (2 hr × $29.92/hr) + (15 hr × $53.32/hr))] for the development of a state's quality rating system.

Under § 438.334(b) each state would collect information from its MCOs, PIHPs, and PAHPs to calculate and then issue a quality rating. We expect that states would rely on information and data already provided to them by their MCOs, PIHPs, and PAHPs; therefore, we do not expect this data collection to pose an additional burden on the private sector. However, each year states would rate each MCO, PIHP, or PAHP with which they contract. We estimate 20 hr at $53.32/hr for a business operations specialist for a state to rate a MCO, PIHP, or PAHP. In aggregate, we estimate an annual state burden of 8,280 hr (414 MCOs, PIHPs, and PAHPs × 20 hr) and $441,489.60 (8,280 hr × $53.32/hr).

To elect the option under § 438.334(c) for states to use their own quality rating system in place of the system under § 438.334(a), a state would submit a request to CMS and receive written CMS approval. Knowing that some states already operate their own quality rating systems, we estimate that one quarter (10) of states will elect to use their own quality rating system. We estimate a one-time state burden of 5 hr at $53.32/hr for a business operations specialist to seek and receive approval from CMS for the state's own quality rating system. In aggregate, we estimate 50 hr (10 states × 5 hr) and $2,666 (50 hr × $53.32/hr).

Section 438.334(d) would provide states with the option to use the MA five-star rating, instead of the quality rating system established under this section, for plans that serve only dual eligibles. We estimate that states may utilize this option for 25 MCOs, PIHPs, or PAHPs. This option would reduce the burden under § 438.334(b) by −500 hr (−25 MCOs, PIHPs, and PAHPs × 20 hr) and −$26,660 (−500 hr × $53.32/hr).

Section 438.334(e) would have states prominently display quality rating information for plans on the state Web site described in § 438.10. The burden associated with this process is captured in § 438.10.

25. ICRs Regarding Managed Care Elements of State Comprehensive Quality Strategies (§ 438.340, Formerly § 438.204)

Section 438.340 would identify the additional items which states that contract with MCOs, PIHPs, and/or PAHPS would include in the comprehensive quality strategy under § 431.502. To include the additional managed care-related items in their comprehensive quality strategies, we estimate a state burden of 10 hr at $53.32/hr for a business operations specialist each time a state revises its comprehensive quality strategy (once every 3 years, per § 431.504(b)). In aggregate, we estimate an annualized burden of 133.3 hr [(40 states × 10 hr)/3 years] and $7,107.56 (133.3 hr × $53.32/hr).

Current regulations at § 438.204(b)(2) describe a quality strategy element, specifically that states contracting with MCOs and/or PIHPs identify the race, ethnicity, and primary language spoken of each Medicaid enrollee, and report this information to MCOs and PIHPs upon enrollment into a plan. We propose removing this item from the proposed managed care elements for a comprehensive quality strategy. The currently approved burden estimates 80 hr per state (for 15 states) to complete the programming necessary to collect and report on these three factors; we would remove this burden, for an aggregate reduction in burden of −1200 hr (15 states × 80 hr).

26. ICRs Regarding Activities Related to External Quality Review (§ 438.358)

Section 438.358(b) describes the mandatory EQR-related activities. These activities may be conducted by the state, its agent that is not an MCO, PIHP, or PAHP, or an EQRO; we will describe the burden assuming that the state conducts these activities. The burden associated with these activities would be the time and effort for a state to conduct and document the findings of the four mandatory activities: (1) The annual validation of PIPs conducted by the MCO, PIHP, or PAHP, (2) the annual validation of performance measures calculated by the MCO, PIHP, or PAHP, (3) a review of MCO, PIHP, or PAHP compliance with structural and operational standards, performed once every 3 years, and (4) validation of MCO, PIHP, or PAHP network adequacy during the preceding 12 months. Each of the activities would be conducted on the 552 MCOs, PIHPs, and PAHPs that we estimate are currently providing Medicaid services.

The types of services provided by MCOs, PIHPs, and PAHPs and the number of PIPs conducted and performance measures calculated will vary. The currently approved burden under control number 0938–0786 (CMS–R–305) for these three activities assumes that each of the then-estimated 458 MCOs and PIHPs validate one PIP by a professional at $63/hr for 65 hr, validate one performance measure by a professional at $63/hr for 53 hr, and complete an annual a compliance review by a professional at $63/hr for 361 hr. The currently approved annual burden is 219,382 hr (479 hr × 458 MCOs and PIHPs) and $13,821,066 (219,382 hr × $63/hr). However, based on recent experience, we estimate that each MCO or PIHP will conduct 3 PIPs, each PAHP will conduct 1 PIP, and that each MCO, PIHP, or PAHP will calculate 3 performance measures. Furthermore, using the time estimates developed for MCOs and PIHPs for the currently approved burden estimates under control number 0938–0786 (CMS–R–305) (and assuming that the same time estimates will also apply to PAHPs), we estimate it would take an average of 65 hr/PIP validation, 53 hr/performance measure validation, and 361 hr/compliance review (occurs once every 3 years) for a business operations specialist, at $53.32/hr, to conduct the mandatory EQR activities. For MCOs and PIHPS, we estimate an annual state burden of 242,367.3 hr (511 MCOs and PIHPs × [(65 hr × 3 PIPs) + (53 hr × 3 performance measures) + (361 hr/3 year)]) and $12,923,024.44 (242,367.3 hr

× $53.32/hr) for the first three mandatory EQR-related activities.

For PAHPs, we estimate an annual state burden of 14,116.3 hr (41 PAHPs × 344.3 hr [(65 hr × 1 PIPs) + (53 hr × 3 performance measures) + (361 hr/3 years)]) and $752,681.12 (14,116.3 hr × $53.32/hr) for the first three mandatory EQR-related activities.

Section 438.358(b)(4) would establish a new mandatory activity (the fourth) to validate MCO, PIHP, and PAHP network adequacy during the preceding 12 months. States would conduct this activity for each MCO, PIHP, and PAHP. Given that this is a new activity, we do not have historic data on which to base an hourly burden estimate for the network validation process. We estimate that it will take less time than the validation of a PIP but more time than the validation of a performance measure. Therefore, we estimate an annual state burden of 60 hr at $53.32/hr for a business operations specialist to support the validation of network adequacy activity. In aggregate, we estimate 33,120 hr (552 MCOs, PIHPs, and PAHPs × 60 hr) and $1,765,958.40 (33,120 hr × $53.32/hr) for the validation of network adequacy activity.

To summarize, for the proposed four mandatory EQR-related activities, we estimate an annual aggregated state burden of 70,221.6 hr [(22,985.3 hr + 14,116.3 hr + 33,120 hr) − 219,382 hr] and $1,620,597.96 [(−$898,041.56 + $752,681.12 + $1,765,958.40) − $13,821,066].

The burden associated with § 438.358(b)(1) through (4) would also include the time for an MCO, PIHP, or PAHP to prepare the information necessary for the state to conduct the mandatory EQR-related activities. We estimate that it would take each MCO, PIHP, or PAHP 200 hr to prepare the documentation for these four activities, half (100 hr) at $53.32/hr by a business operations specialist and half (100 hr) at $29.92/hr by an office and administrative support worker. In aggregate, we estimate an annual private sector burden of 110,400 hr (552 MCOs, PIHPs, and PAHPs × 200 hr) and $4,594,848 [(55,200 hr × $53.32/hr) + (55,200 hr × $29.92/hr)]. However, the currently approved burden under control number 0938–0786 (CMS–R–305) estimates 160 hr per MCO or PIHP to prepare the information for the three existing mandatory EQR-related activities (§ 438.358(b)(1) through (3)), half by a professional at $63/hr and half by clerical staff at $12/hr, The currently approved burden for information preparation is 73,280 hr (438 MCOs and PIHPs × 160 hr) and $2,748,000 [(36,640 hr × $63/hr) + (36,640 hr × $12/hr)]. When comparing the currently approve burden against this rule's proposed burden, we estimate a net burden of 37,120 hr (110,400 hr − 73,280 hr) and $1,846,848 ($4,594,848 − $2,748,000) for the preparation of information for the mandatory EQR-related activities described in § 438.358(b)(1) through (4).

Section 438.358(c) describes the five optional EQR-related activities: (1) Validation of client level data (such as claims and encounters); (2) administration or validation of consumer or provider surveys; (3) calculation of performance measures; (4) conduct of PIPs; and (5) conduct of focused studies. As with the mandatory activities described in § 438.358(b), these activities may be conducted by the state, its agent that is not an MCO, PIHP, or PAHP, or an EQRO, but for the purposes of this burden estimate we assume that the state conducts the activities.

We have no data to estimate the hours associated with how long it will take to conduct the optional EQR activities. Without that information, we estimate is that it would take 350 hr to validate client level data and 50 hr to validate consumer or provider surveys. We estimate it would take three times as long to calculate performance measures as it takes on average to validate (159 hr) and three times as long to conduct PIPs and focused studies as it takes on average to validate PIPs (195 hr). We also estimate that it would take three times as long to administer a consumer or provider survey than it takes to validate a survey (150 hr).

The currently approved burden under control number 0938–0786 (CMS–R–305) uses state-reported data from 2001 to estimate that states will: (1) Validate the encounter data of 69 percent (316) of MCOs and PIHPs; (2) administer or validate consumer or provider surveys of 43 percent (197) of MCOs and PIHPs; (3) calculate performance measures of 29 percent (133) of MCOs and PIHPs; (4) conduct PIPs of 38 percent (174) of MCOs and PIHPs; and (5) conduct focused studies of 76 percent (348) of MCOs and PIHPs. Using the hourly estimates (above) for each task and assuming the work is completed by a professional at $63/hr, CMS–R–305 estimates a total burden of 240,759 hr and $15,167,817. However, based on our review of EQR technical report submissions since the original promulgation of these regulations, we have observed that many states do not conduct the optional EQR-related activities as frequently as assumed in our original estimates. While the exact states and number vary from year to year, we have not observed participation at the level observed in 2001 state-reported data. Therefore, we revise our estimate and assume that 10 percent (51) of MCOs and PIHPs will be subject to each of the optional EQR-related activities. Regarding the administration or validation of consumer or provider surveys, we assume that half of the MCOs and PIHPs (25) will administer surveys while half (26) will validate surveys. We also estimate that a mix of professionals will work on each optional EQR-related activity: 20 percent by a general and operations manager ($127.72/hr); 25 percent by a computer programs ($73.60/hr); and 55 percent by a business operations specialist ($53.32/hr).

To validate client level data, we estimate 17,850 hr (51 MCOs and PIHPs × 350 hr) and $1,307,869.50 [(17,850 hr × 20 percent × $127.72/hr) + (17,850 hr × 25 percent × $73.60/hr) + (17,850 hr × 55 percent × $53.32/hr)]. To administer consumer or provider surveys, we estimate 3,750 hr (25 MCOs and PIHPs × 150 hr) and $274,762.50 [(3,750 hr × 20 percent × $127.72/hr) + (3,750 hr × 25 percent × $73.60/hr) + (3,750 hr × 55 percent × $53.32/hr)]. To validate consumer or provider surveys, we estimate 1,300 hr (26 MCOs and PIHPs × 50 hr) and $95,251 [(1,300 hr × 20 percent × $127.72/hr) + (1,300 hr × 25 percent × $73.60/hr) + (1,300 hr × 55 percent × $53.32/hr)]. To calculate performance measures, we estimate 8,109 hr (51 MCOs and PIHPs × 159 hr) and $594,146.43 [(8,109 hr × 20 percent × $127.72/hr) + (8,109 hr × 25 percent × $73.60/hr) + (8,109 hr × 55 percent × $53.32/hr)]. To conduct PIPs, we estimate 9,945 hr (51 MCOs and PIHPs × 195 hr) and $728,670.15 [(9,945 hr × 20 percent × $127.72/hr) + (9,945 hr × 25 percent × $73.60/hr) + (9,945 hr × 55 percent × $53.32/hr)]. To conduct focused studies, we estimate 9,945 hr (51 MCOs and PIHPs × 195 hr) and $728,670.15 [(9,945 hr × 20 percent × $127.72/hr) + (9,945 hr × 25 percent × $73.60/hr) + (9,945 hr × 55 percent × $53.32/hr)]. In aggregate, the annual burden for optional EQR-related activities for MCOs and PIHPs is 50,899 hr (17,850 hr + 3,750 hr + 1,300 hr + 8,109 hr + 9,945 hr + 9,945 hr) and $3,729,369.73 [(50,899 hr × 20 percent × $127.72/hr) + (50,899 hr × 25 percent × $73.60/hr) + (50,899 hr × 55 percent × $53.32/hr)].

Section 438.358(c) would also be revised to include PAHPs. Since PAHPs are not currently subject to EQR, we do not have any data on which to base an estimate regarding how states would apply the optional EQR-related activities. Therefore, we will apply the time, wage, and participation estimates

developed for MCOs and PIHPs to PAHPs. To validate client level data, we estimate 1,400 hr (4 PAHPs × 350 hr) and $102,578 [(1,400 hr × 20 percent × $127.72/hr) + (1,400 hr × 25 percent × $73.60/hr) + (1,400 hr × 55 percent × $53.32/hr)]. To administer consumer or provider surveys, we estimate 300 hr (2 PAHPs × 150 hr) and $21,981 [(300 hr × 20 percent × $127.72/hr) + (300 hr × 25 percent × $73.60/hr) + (300 hr × 55 percent × $53.32/hr)]. To validate consumer or provider surveys, we estimate 100 hr (2 PAHPs × 50 hr) and $7,327 [(100 hr × 20 percent × $127.72/hr) + (100 hr × 25 percent × $73.60/hr) + (100 hr × 55 percent × $53.32/hr)]. To calculate performance measures, we estimate 636 hr (4 PAHPs × 159 hr) and $46,599.72 [(636 hr × 20 percent × $127.72/hr) + (636 hr × 25 percent × $73.60/hr) + (636 hr × 55 percent × $53.32/hr)]. To conduct PIPs, we estimate 780 hr (4 PAHPs × 195 hr) and $57,150.60 [(780 hr × 20 percent × $127.72/hr) + (780 hr × 25 percent × $73.60/hr) + (780 hr × 55 percent × $53.32/hr)]. To conduct focused studies, we estimate 780 hr (4 PAHPs × 195 hr) and $57,150.60 [(780 hr × 20 percent × $127.72/hr) + (780 hr × 25 percent × $73.60/hr) + (780 hr × 55 percent × $53.32/hr)]. In aggregate, the total annual burden for optional EQR-related activities for PAHPs is 3,996 hr (1,400 hr + 300 hr + 100 hr + 636 hr + 780 hr + 780 hr) and $292,786.92 [(3,996 hr × 20 percent × $127.72/hr) + (3,996 hr × 25 percent × $73.60/hr) + (3,996 hr × 55 percent × $53.32/hr)].

27. ICRs Regarding Nonduplication of Mandatory Activities (§ 438.360)

Section 438.360(a) would grant states the option to use the information obtained from a Medicare or private accreditation review of an MCO, PIHP, or PAHP in place of information otherwise generated from the three mandatory activities specified in § 438.358(b)(1) through (3). The proposed revisions would: (1) Allow states to apply the non-duplication option to PAHPs, in addition to MCOs and PIHPs; (2) allow states to apply the non-duplication option to the validation of performance measures and PIPs, in addition to the compliance review, for all MCOs, PIHPs, and PAHPs; (3) remove current § 438.360(c), as there would no longer be a difference in the application of non-duplication to plans serving only dual eligibles; and (4) combine current § 438.360(b)(4) and (c)(4) into proposed § 438.360(c), to maintain a discussion of non-duplication as an element of the comprehensive quality strategy.

Section 438.360(b) would describe when a state could elect to use information from a Medicaid or private accreditation review in place of information that would otherwise be generated by the mandatory EQR-related activities in § 438.358(b)(1) through (3). The burden associated with non-duplication is the time and effort for an MCO, PIHP, or PAHP to disclose the reports, findings, and other results of the Medicare or private accreditation review to the state agency.

While states could elect to allow all 552 MCOs, PIHPs, and PAHPs to substitute information from a Medicare or private accreditation review for the three mandatory EQR-related activities specified at § 438.358(b)(1) through (3), in practice we find that states utilize this option infrequently. Therefore, we estimate that states would apply the non-duplication option to 10 percent (55) of MCOs (33), PIHPs (18), and PAHPs (4). The currently approved burden under control number 0938–0786 (CMS–R–305)) estimates that 336 MCOs and/or PIHPs take advantage of the nonduplication provision, requiring 8 hr at $37.50/hr per MCO or PIHP to disclose the necessary information to the state, for a total currently approved burden of 2,688 hr (336 MCOs and PIHPs × 8 hr) and $100,800 (2,688 hr × $37.50/hr). Since this appears to be an overestimate of the burden for MCOs and PIHPs, we estimate a revised annual private sector burden of 2 hr at $53.32/hr for a business operations specialist and 6 hr at $29.92/hr for an office and administrative support worker to disclose the necessary documentation to the state each year for a single MCO or PIHP. In aggregate, we estimate 408 hr (51 MCOs and PIHPs × 8 hr) and $14,594.16 [(51 MCOs and PIHPs × (2 hr × $53.32/hr) + (6 hr × $29.92/hr)]. Under this proposal, states could apply the nonduplication provisions to PAHPs. In aggregate, we estimate 32 hr (4 PAHPs × 8 hr) and $1,144.64 [4 PAHPs × (2 hr × $53.32/hr) + (6 hr × $29.92/hr)].

The process in § 438.360(b) would include having a state agency provide all of the reports, findings, and other results of the Medicare or private accreditation review to the appropriate EQRO. The currently approved burden under control number 0938–0786 (CMS–R–305) estimates that sharing the reports, findings, and results with EQROs for 336 MCOs and PIHPs would take states 8 hr at $37.50/hr per plan, for a total burden of 2,688 hr (336 MCOs × 8 hr) and $100,800 (2,688 hr × $37.50/hr). However, we estimate it would take, on average, 2 hr at $29.92/hr for an office and administrative support worker to disclose the necessary documentation to the appropriate EQRO. This represents a decrease in the estimated hourly burden for this task, as we believe that the use of electronic tracking and transmission tools has significantly decreased the hourly burden associated with state staff forwarding the documentation to the EQRO. In aggregate, we estimate an annual state burden of 110 hr (55 MCOs, PIHPs, and PAHPs × 2 hr) and $3,291.20 (110 hr × $29.92/hr) to forward non-duplication-related documentation to the EQROs.

Assuming that states would apply the non-duplication provision to 10 percent of MCOs, PIHPs, and PAHPs, we estimate that this provision would offset the burden associated with § 438.358(b)(1) through (3) for 51 MCOs and PIHPs, and 4 PAHPs (since these activities would no longer be necessary for these 55 plans). Consistent with the estimates used in § 438.358(b)(1) through (3), we estimate an aggregated offset of –25,566.50 hr [(−51 MCOs and PIHPs × 474.3 hr) + (−4 PAHPs × 344.3 hr)] and −$1,363,205.78 (−25,566.50 hr × $53.32).

Additionally, the MCOs, PIHPs, and PAHPs subject to non-duplication would not have to prepare the documentation necessary for the three mandatory EQR-related activities. Based on the assumption in § 438.358(b) that an MCO, PIHP, or PAHP would need 200 hr to prepare the documentation for the four mandatory activities, we estimate that it would take 150 hr to prepare the documentation for the three activities subject to non-duplication, half (100 hr) at $53.32/hr by a business operations specialist and half (100 hr) at $29.92/hr by an office and administrative support worker. In aggregate, we estimate a decrease in annual private sector burden of −8,250 hr (−55 MCOs, PIHPs, and PAHPs × 150 hr) and −$343,365 [(−4,125 hr × $53.32/hr) + (−4,125 × $29.92)].

28. ICRs Regarding Exemption From External Quality Review (§ 438.362)

Section 438.362 would be modified to reflect that PIHPs cannot be exempted from EQR, as they do not qualify as a MA Organization under part C of Title XVII of the Act or under section 1876 of the Act, and they do not qualify as an MCO under section 1903(m) of the Act. This would lead to a decrease in our estimate of the number of plans that might be exempt from the EQR process.

Under § 438.362, exempted MCOs would have to provide (annually) to the state agency the most recent Medicare review findings reported to the MCO by CMS or its agent. Of the approximately 335 MCOs, we estimate that

approximately half (168) might provide Medicare services in addition to Medicaid services. Of these 168 MCOs that might potentially provide Medicare services in addition to Medicaid services, we further estimate that state agencies would allow approximately 10 percent (17) of the MCOs to be exempt from the EQR process.

We estimate an annual private sector burden of 8 hr (2 hr at $53.32/hr for a business operations specialist and 6 hr at $29.92/hr for an office and administrative support worker) for an MCO to prepare and submit the necessary documentation to the state agency. In aggregate, we estimate 136 hr (17 MCOs × 8 hr) and $4,864.72 (17 MCOs × [(2 hr × $53.32/hr) + (6 hr × $29.92/hr)]).

The currently approved burden under control number 0938–0786 (CMS–R–305) estimates that states would allow 10 percent (20) of the 202 MCOs (which might provide Medicare services in addition to Medicaid services) to be exempt from the EQR process, and that it would take each MCO approximately 8 hr at $37.50/hr to prepare the necessary materials for a total burden of 160 hr (20 MCOs × 8 hr) and $6,000 (160 hr × $37.50/hr).

Therefore, we estimate a net burden of −24 hr (136 hr − h160 hr) and −$1,135.28 ($4,864.72 − $6,000).

29. ICRs Regarding External Quality Review Results (§ 438.364)

Section 438.364(a) would describe the information that would be included in the annual detailed technical report that is the product of the EQR. Section 438.364(a)(1)(iii) would specify that the EQR technical report include baseline and outcomes data regarding PIPs and performance measures. Many states already provide much of this information in their final EQR technical report. The burden of compiling this data for MCOs, PIHPs, and PAHPs is captured in § 438.358. Under § 438.364(a)(3), EQR technical reports would include recommendations on how the state can use the goals and objectives of its comprehensive quality strategy to support improvement in the quality, timeliness, and access to care for beneficiaries. We believe that states would amend their EQRO contracts to address the changes to § 438.364(a). We estimate a one-time state burden of 0.5 hr at $53.32/hr for a business operations specialist to amend the EQRO contract. In aggregate, we estimate 20 hr (40 states × 0.5 hr) and $1,066.40 (20 hr × $53.32/hr).

Section 438.364(b)(1) would clarify that the EQRO would produce and submit to the state an annual EQR technical report, and that states may not substantively revise the report without evidence of error or omission, or permission from CMS. This is consistent with existing policy and should not pose a burden on the states or the private sector. The proposed April 30th deadline for the finalization and submission of EQR technical reports is consistent with existing subregulatory guidance.

While we do not anticipate that these changes would pose a significant burden on states or the private sector, we estimate that this provision may necessitate a change in a state's EQRO contract for approximately 10 states. In this regard, we estimate a one-time state burden of 0.5 hr at $53.32/hr for a business operations specialist to modify the EQRO contract. In aggregate, we estimate 5 hr (10 states × 0.5 hr) and $266.60 (5 hr × $53.32/hr).

Under § 438.364(b)(2), each state agency would provide copies of technical reports, upon request, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO, PIHP, or PAHP, beneficiary advocacy groups, and members of the general public. States would also make the most recent EQR technical report publicly available on the state's Web site, the burden for which is included in § 438.10.

We believe that by making these reports available online, states would be able to significantly decrease the burden associated with responding to requests from the public for this information, as it will already be easily accessible. The burden associated with section is the time and effort for a state agency to furnish copies of a given technical report to interested parties. The currently approved burden under control number 0938–0786 (CMS–R–305) estimates a burden of 91,600 hr and $1,099,200. This assumed 329 MCOs and 129 PIHPs (for a total of 458), 25 requests per MCO or PIHP, and 8 hr to respond to each request by staff at $12/hr. In light of recent technological changes described in this section of this proposed rule, we estimate an annual state burden of 5 min (on average) at $29.92/hr for an office and administrative support worker to disclose the reports (per request), and that a state would receive 5 requests per MCO, PIHP, or PAHP per year. In aggregate, we estimate 230 hr [(552 MCOs, PIHPs, and PAHPs × 5 requests × 5 min)/60 min] and $6,881.60 (230 hr × $29.92/hr). Overall, we estimate a net burden of −91,370 hr (230 hr − 91,600 hr) and −$1,092,318.40 ($6,881.60 − $1,099,200).

30. ICRs Regarding Federal Financial Participation (§ 438.370)

Section 438.370(c) would have states submit their EQRO contracts to CMS for review and approval prior to claiming FFP at the 75 percent rate. Since most states already consult with CMS regarding EQRO contracts, we estimate only 12 states will need to amend their policies and procedures to comply with this process. We estimate a one-time state burden of 0.5 hr at $53.32/hr for a business operations specialist to amend their state's policies and procedures. In aggregate, we estimate 6 hr (12 states × 0.5 hr) and $319.92 (6 hr × $53.32/hr).

The 12 states which do not currently work with CMS on their EQRO contracts would need to submit the EQRO contracts to CMS for review and approval if they plan to claim the enhanced 75 percent federal match. We estimate 0.25 hr at $29.92/hr for an office and administrative support worker to submit the EQRO contract to CMS. In aggregate, we estimate 3 hr (12 states × 0.25 hr) and $89.76 (3 hr × $29.92/hr).

31. ICRs Regarding Statutory Basis and Definitions (§ 438.400)

Section 438.400(b) would replace ''action'' with ''adverse benefit determination'' and revise the definition. It would also revise the definitions of ''appeal'' and ''grievance'' and add a definition for ''grievance system.'' In response, states, MCOs and PIHPs would need to update any documents where these terms are used. (PAHPs will use these updated definitions when they develop their systems in § 438.402.)

We estimate a one-time private sector burden of 5 hr at $53.32/hr for a business operations specialist to amend all associated documents to the new nomenclature and definitions. In aggregate, we estimate 2,535 hr (507 MCO and PIHP entities × 5 hr) and $135,166.20 (2,535 hr × $53.32/hr). We also estimate a one-time state burden for states of 200 hr (40 states × 5 hr) and $10,664 (200 hr × $53.32/hr) to make similar revisions.

32. ICRs Regarding General Requirements for Grievance System (§ 438.402)

Section 438.402(a) would add PAHPs to the existing requirement for MCOs and PIHPs to have a grievance system. There are 41 non-NEMT PAHPs that would need to have their contract amended. The burden for revising their contract is included in § 438.3.

To set up a grievance system, we estimate it would take 100 hr (10 hr at

$127.72/hr for a general and operations manager, 75 hr at $53.32/hr for a business operations specialist, and 15 hr at $73.60/hr for a computer programmer) for each PAHP. In aggregate, we estimate a one-time private sector burden of 4,100 hr (41 PAHPs × 100 hr) and $261,383.20 [41 PAHPs × ((10 hr × $127.72/hr) + (75 hr × $53.32/hr) + (15 hr × $73.60/hr))].

We further estimate that the average PAHP would only receive 10 grievances per month due to their limited benefit package and will only require 3 hr at $53.32/hr for a business operations specialist to process and handle grievances and adverse benefit determinations. In aggregate, we estimate an annual private sector burden of 14,760 hr (41 PAHPs × 10 grievances × 3 hr × 12 months) and $787,003.20 (14,760 hr × $53.32/hr).

Section 438.402(b) would limit MCOs, PIHPs, and PAHPs to one level of appeal for enrollees. This will likely eliminate a substantial amount of burden from those that currently have more than one, but we are unable to estimate that amount since we do not know how many levels each managed care plan currently utilizes. We request comment from managed care plans to help us estimate the savings from this provision.

33. ICRs Regarding Timely and Adequate Notice of Adverse Benefit Determination (§ 438.404)

Section 438.404(a) would add PAHPs as an entity that must give the enrollee timely written notice. It also sets forth the requirements of that notice. Consistent with the requirements for MCOs and PIHPs, PAHPs must give the enrollee timely written notice if it intends to: Deny, limit, reduce, or terminate a service; deny payment; deny the request of an enrollee in a rural area with one plan to go out of network to obtain a service; or fails to furnish, arrange, provide, or pay for a service in a timely manner.

We estimate an annual private sector burden of 1 min at $26.40/hr for a mail clerk to send this notification. We also estimate that 2 percent (240,000) of the 12 million PAHP enrollees will receive one notice of adverse benefit determination per year from a PAHP. In aggregate, we estimate an annual state burden of 4,000 hr (240,000 enrollees × 1 min) and $105,811.20 (4,000 hr × $26.40/hr).

34. ICRs Regarding Resolution and Notification: Grievances and Appeals (§ 438.408)

Section 438.408(b) would change the time frame for appeal resolution from 45 days to 30 days. For MCOs, PIHPs, and PAHPs that have Medicare and/or QHP lines of business, this reflects a reduction in burden as this would align Medicaid time frames with Medicare and QHP. For MCOs, PIHPs, and PAHPs that do not have Medicare and/or QHP lines of business, and whose state has an existing time frame longer than 30 days, they would need to revise their policies and procedures. Among the 200 MCOs, PIHPs, and PAHPs, we estimate a one-time private sector burden of 1 hr at $53.32/hr for a business operations specialist. In aggregate, we estimate 200 hr (200 MCOs, PIHPs, and PAHPs × 1 hr) and $10,664 (200 hr × $53.32).

35. ICRs Regarding Recordkeeping Requirements (§ 438.416)

This section would add PAHPs to the requirement to maintain records of grievances and appeals. We estimate that approximately 240,000 enrollees (2 percent) of the approximately 12 million PAHP enrollees file a grievance or appeal with their PAHP. As the required elements will be stored and tracked electronically, we estimate 1 min per grievance and appeal at $29.92/hr for an office and administrative support worker to maintain each grievance and appeals record. In aggregate, we estimate an annual private sector burden of 4,000 hr (240,000 grievances × 1 min) and $119,919.36 (4,000 hr × $29.92/hr).

Maintaining records for grievances and appeals has always been required for MCOs and PIHPs. However, we propose specific data so MCOs and PIHPs will have to revise their policies and systems to record the required information. We estimate 3 hr at $73.60 for a computer programmer to make necessary changes. We estimate a one-time private sector burden of 168 hr (56 MCOs and PIHPs × 3 hr) and $12,364.80 (168 hr × $73.60/hr). As the required elements will be stored and tracked electronically, we estimate 1 min per grievance and appeal at $29.92/hr for an office and administrative support worker to maintain each grievance and appeals record. In aggregate, we estimate an annual private sector burden of 14,271 hr (856,257 grievances × 1 min) and $426,986.82 (14,271 hr × $29.92/hr).

Section 438.420(c)(4) would remove the ''time period or service limit of a previously authorized service has been met'' as a criteria for defining the duration of continued benefits and would add ''PAHP'' as a conforming change to § 438.400. This action would require that MCOs and PIHPs revise current policies and procedures to reflect having only 3 criteria instead of 4. PAHPs would incorporate the options in § 438.420(c)(1) through (3) when developing their system under § 438.402 and thus the elimination of paragraph (c)(4) would have no impact on PAHPs.

For MCOs and PIHPs, we estimate a one-time private sector burden of 4 hr at $53.32/hr for a business operations specialist to revise current policies and procedures. In aggregate, we estimate 2,028 hr (507 MCOs and PIHPs × 4 hr) and $108,132.96 (2,028 hr × $53.32/hr).

Section 438.420(d) would add PAHPs to the list of entities that can recover costs if the adverse determination is upheld. PAHPs would include the policies and procedures necessary to recover costs when developing their system under § 438.402 and thus would incur no additional burden.

36. ICRs Regarding State Responsibilities (§ 438.602)

Section 438.602(a) would detail state responsibilities for monitoring MCO, PIHP, PAHP, PCCM or PCCM's compliance with §§ 438.604, 438.606, 438.608, 438.610, 438.230, and 438.808. As all of these sections are existing requirements, the only new burden is for states to update their policies and procedures, if necessary, to reflect revised regulatory text. We estimate a one-time state burden of 6 hr at $53.32/hr for a business operations specialist to create and/or revise their policies. In aggregate, we estimate 252 hr (42 states × 6 hr) and $13,436.64 (252 hr × $53.32/hr).

Section 438.602(b) would require states to screen and enrollee MCO, PIHP, PAHP, PCCM and PCCM entity providers in accordance with 42 CFR part 455, subparts B and E. Given that states already comply with these subparts for their FFS programs, the necessary processes and procedures have already been implemented. Additionally, since some states require their managed care plan providers to enroll with FFS, the overlap that occurs in many states due to provider market conditions, and the exemption from this requirement for Medicare approved providers, we believe the pool of managed care providers that will have to be newly screened and enrolled by the states is small. Since we do not have data on which to base our estimate, we seek comment from states on the quantity of managed care providers that would require screening and enrollment. We expect the MCOs, PIHPs, and PAHPs will need to create data files to submit new provider applications to the state for the screening and enrollment processes. As PCCMs and PCCM entities are already FFS providers, there would be no additional burden on them or the state.

As such, we estimate a one-time private sector burden of 6 hr at $73.60/hr for a computer programmer to create the necessary programs to send provider applications/data to the state. In aggregate, we estimate 3,408 hr (568 MCOs, PIHPs, and PAHPs × 6 hr) and $250,828.80 (3,408 hr × $73.60/hr). Once created, the report would likely be put on a production schedule and generate no additional burden.

Section 438.602(e) would require states to conduct or contract for audits of MCO, PIHP, and PAHP encounter and financial data once every 3 years. As validation of encounter data is also required in § 438.818(a), we assume no additional burden. For the financial audits, states could use internal staff or an existing contractual resource, such as their actuarial firm. For internal staff, we estimate an annual state burden of 20 hr at $63.10/hr for an accountant. In aggregate, we estimate 3,787 hr (568 MCOs, PIHPs, and PAHPs × 20 hr)/3) and $238,959.70 (3,787 hr × $63.10/hr).

Section 438.602(g) would require states to post the MCO's, PIHP's, and PAHP's contracts, data from § 438.604, and audits from § 438.602(e) on their Web site. As most of these activities will only occur no more frequently than annually, we estimate an annual state burden of 1 hr at $73.60/hr for a computer programmer to post the documents. In aggregate, we estimate 40 hr (40 states × 1 hr) and $2,944 (40 hr × $73.60/hr).

37. ICRs Regarding Program Integrity Requirements (§ 438.608)

Section 438.608(a) would require that MCOs, PIHPs, and PAHPs have administrative and management arrangements or procedures that are designed to guard against fraud and abuse. The arrangements or procedures must include a compliance program as set forth under § 438.608(a)(1), provisions for reporting under § 438.608(a)(2), provisions for notification under § 438.608(a)(3), provisions for verification methods under § 438.608(a)(4), and provisions for written policies under § 438.608(a)(5).

The compliance program must include: Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable federal and state standards and requirements under the contract; the designation of a Compliance Officer; the establishment of a Regulatory Compliance Committee on the Board of Directors; effective training and education for the organization's management and its employees; and provisions for internal monitoring and a prompt and effective response to noncompliance with the requirements under the contract.

While § 438.608(a)(1) is an existing regulation, we expect all MCOs, PIHPs, and PAHPs review their policies and procedures to ensure that all of the above listed items are addressed. We estimate a one-time private sector burden of 2 hr at $53.32/hr for a business operations specialist to review and (if necessary) revise their policies and procedures. In aggregate, we estimate 1,136 hr (568 MCOs, PIHPs, and PAHPs × 2 hr) and $60,571.52 (1,136 hr × $53.32/hr).

Section 438.608(a)(2) and (3) require reporting of improper payments and enrollee fraud. As these would be done via an email from the MCO, PIHP, or PAHP to the state and do not occur very often, we estimate an annual private sector burden of 2 hr at $53.32/hr for a business operations specialist. In aggregate, we estimate 1,136 hr (568 MCOs, PIHPs, and PAHPs × 2 hr) and $60,571.52 (1,136 hr × $53.32/hr).

Section 438.608(a)(4) would require the MCO, PIHP, or PAHP to use a sampling methodology to verify receipt of services. Given that this is already required of all states in their FFS programs, many states already require their MCOs, PIHPs, and PAHPs to do this. Additionally, many health plans perform this as part of usual and customary business practice. Therefore, we estimate only approximately 200 MCOs, PIHPs, or PAHPs may need to implement this as a new procedure. As this typically involves mailing a letter or sending an email to the enrollee, we estimate that 200 MCOs, PIHPs, or PAHPs would mail to 100 enrollees each. We estimate an annual private sector burden of 1 min at $26.40/hr for a mail clerk to send each letter. In aggregate, we estimate 333 hr (20,000 letters × 1 min/letter) and $8,817.60 (333 hr × $26.40/hr). This estimate will be significantly reduced as the use of email increases.

Section 438.608(b) reiterates the requirement in § 438.602(b) whereby the burden is stated in section IV.B.36. of this proposed rule.

Section 438.608(c) and (d) would require states to include in all MCO, PIHP, and PAHP contracts, the process for the disclosure and treatment of certain types of recoveries and reporting of such activity. While the burden to amend the contracts is included in § 438.3, we estimate a one-time private sector burden of 1 hr at $73.60/hr for a computer programmer to create the report. In aggregate, we estimate 568 hr (568 MCOs, PIHPs, and PAHPs × 1 hr) and $41,804.80 (568 hr × $73.60/hr). Once developed, the report would be put on a production schedule and add no additional burden.

38. ICRs Regarding Disenrollment During Termination Hearing Process (§ 438.722)

After a state has notified an MCO, PIHP, PAHP or PCCM of its intention to terminate its contract, § 438.722(a) would provide that the state may give the entity's enrollees written notice of the state's intent to terminate its contract. States already have the authority to terminate contracts according to state law and they have already opted to provide written notice to MCO and PCCM enrollees.

We estimate that no more than 12 states may terminate 1 contract per year. We also estimate an annual state burden of 1 hr at $53.32/hr for a business operations specialist to prepare the notice. In aggregate, we estimate a one-time state burden of 12 hr (12 states × 1 hr) and $639.84 (12 hr × $53.32/hr).

To send the notice, we estimate 1 min (per beneficiary) at $26.40/hr for a mail clerk. We estimate an aggregate annual state burden of 18,075 hr (12 states × 90,378 enrollees/60 mins) and $477,195 (18,075 hr × $26.40/hr).

39. ICRs Regarding Enrollee Encounter Data (§ 438.818)

Section 438.818(a)(2) would require that the encounter data be validated prior to its submission. States can perform this validation activity themselves, contract it to a vendor, or contract it to their External Quality Review Organization (EQRO). In this regard, a state already using EQRO to validate its data at an appropriate frequency would incur no additional burden. Since approximately 10 states already use their EQRO to validate their data, only 27 states may need to take action to meet this requirement. The method selected by the state will determine the amount of burden incurred. We assume an equal distribution of states selecting each method, thus 9 states per method.

A state using EQRO to validate data on less than an appropriate frequency may need to amend their EQRO contract. In this case, we estimate 1 hr at $53.32/hr for a business operations specialist. In aggregate, we estimate a one-time state burden of 9 hr (9 states × 1 hr) and $479.88 (9 hr × $53.32/hr).

A state electing to perform validation internally would need to develop processes and policies to support implementation. In this case, we estimate 10 hr at $53.32/hr for a business operations specialist to develop policy and 100 hr at $73.60/hr for a computer programmer to develop,

test, and automate the validation processes. In aggregate, we estimate a one-time state burden of 990 hr (9 states × 110 hr) and $71,038.80 [9 states × ((10 hr × $53.32/hr) + (100 hr × $73.60/hr))].

For a state electing to procure a vendor, given the wide variance in state procurement processes, our burden is conservatively estimated at 150 hr for writing a proposal request, evaluating proposals, and implementing the selected proposal. We estimate 75 hr at $53.32/hr for a business operations specialist to participate in the writing, evaluating, and implementing, 50 hr at $53.32/hr for a business operations specialist to participate in the writing, evaluating, and implementing, and 25 hr at $127.72/hr for a general and operations manager to participate in the writing, evaluating, and implementing. In aggregate, we estimate an annual state burden of 1,350 hr [9 states × (150 hr)] and $88,722 [9 states × ((125 hr × $53.32/hr) + (25 hr × $127.72/hr))].

40. ICRs Regarding CHIP Component of the State Comprehensive Quality Strategy.

Per § 457.760, states would address all delivery systems for their CHIP programs as a component of the state comprehensive quality strategy under part 431, subpart I. While the majority of the burden associated with the comprehensive quality strategy is captured in part 431, subpart I, we estimate an additional burden of 10 hr (every 3 years) at $53.32/hr for a business operations specialist to address CHIP within the comprehensive quality strategy. In aggregate, we estimate an annualized burden of 110 hr [(33 states and territories × 10 hr)/3 years] and $5,864.61 (110 hr × $53.32/hr).

41. ICRs Regarding Standard Contract Requirements (§§ 457.1201, 457.1205, 457.1207, 457.1208, 457.1210, 457.1212, 457.1218, 457.1220, 457.1222, 457.1224, 457.1226, 457.1228, 457.1230, 457.1233, 457.1240, 457.1250, 457.1260, 457.1270, and 457.1285)

Section 457.1201 would provide a list of standard requirements that must be included in MCO, PIHP, PAHP, and PCCM contracts. The following burden estimate addresses the effort to amend such contracts in addition to the contract amendments associated with §§ 457.1205, 457.1207, 457.1208, 457.1210, 457.1212, 457.1218, 457.1220, 457.1222, 457.1224, 457.1226, 457.1228, 457.1230, 457.1233, 457.1240, 457.1250, 457.1260, 457.1270, and 457.1285. We estimate a one-time state burden of 6 hr at $53.32/hr for a business operations specialist to amend all contracts associated with the aforementioned requirements. In aggregate, we estimate 396 hr (66 contracts × 6 hr) and $21,114.72 (396 hr × $53.32/hr).

42. ICRs Regarding Medical Loss Ratio (§ 457.1205)

Section 457.1205 would apply the requirements of § 438.8 to CHIP. Section 438.8(c) would require that MCOs, PIHPs, and PAHPs report to the state annually their total expenditures on all claims and non-claims related activities, premium revenue, the calculated MLR, and, if applicable under other authority, any remittance owed.

We estimate the total number of MLR reports that MCOs, PIHPs, and PAHPs would be required to submit to the state would amount to 62 contracts. We estimate a one-time burden of 168 hr for the initial administration activities. In the first year, we estimate that 60 percent of the time would be completed by a computer programmer (101 hr at $73.60/hr), 30 percent would be completed by a business operations specialist (50 hr at $53.32/hr), and 10 percent would be completed by a general and operations manager (17 hr at $127.72/hr). The first year burden amounts to 168 hr and $12,270.84 ((101 hr × $73.60) + (50 hr × $53.32) + (17 hr × $127.72)) per report or, in aggregate, 10,416 hr (62 reports × 168 hr) and $760,792.086 (62 × $12,270.84).

In subsequent years, since the programming and processes established in year 1 will continue to be used, the burden will be decrease from 168 hr to an ongoing burden of approximately 53 hr. Using the same proportions of labor allotment, we estimate 53 hr and $3,865.18 ((31.8 hr × $73.60) + (15.9 hr × $53.32) + (5.3 hr × $127.72)) per report and a total of 3,127 hr (53 hr × 59 reports) and $228,045.62 (59 reports × $3,865.18). We expect states to permit MCOs and PIHPs to submit the report electronically. Since the submission time is included in our reporting estimate, we are not setting out the burden for submitting the report.

43. ICRs Regarding Non-Emergency Medical Transportation PAHPs (§ 457.1206)

Section 457.1206 would provide a list of standard requirements that must be included in NEMT PAHP contracts. The following burden estimate addresses the effort to amend such contracts in addition to the contract amendments associated with §§ 457.1205, 457.1207, 457.1210, 457.1212, 457.1220, 457.1222, 457.1224, 457.1226, 457.1230, and 457.1233. We estimate a one-time state burden of 4 hr at $53.32/hr for a business operations specialist to amend all contracts associated with the aforementioned requirements. In aggregate, we estimate 12 hr (3 contracts × 4 hr) and $639.84 (12 hr × $53.32/hr).

44. ICRs Regarding Information Requirements (§ 457.1207)

Section 457.1207 would apply the requirements of § 438.10 to CHIP. Section 438.10(c)(1) would require that states provide enrollment notices, informational materials, and instructional materials in an easily understood format. We anticipate that most states already do this and will only have to make minor revisions. We estimate an annual burden of 4 hr at $53.32/hr for a business operations specialist to make these revisions. In aggregate, we estimate 132 hr (33 states × 4 hr) and $7,038.24 (132 hr × $53.32/hr).

Section 438.10(c)(3) would require that states operate a Web site which provides the information set out under § 438.10(f). Since all states already have Web sites for their Medicaid programs and most also include information about their managed care program, most states will probably only have to make minor revisions to their existing Web site. We estimate a one-time state burden of 6 hr at $73.60/hr for a computer programmer to make the initial changes. In aggregate, we estimate 198 hr (33 states × 6 hr) and $14,572.80 (198 hr × $73.60/hr). We also estimate an annual burden of 3 hr at $73.60/hr for a computer programmer to periodically add or update documents and links on the Web site. In aggregate, we estimate 99 hr (33 states × 3 hr) and $7,286.40 (99 hr × $73.60/hr).

Section 438.10(c)(4)(i) would recommend that states develop definitions for commonly used terms to enhance consistency of the information provided to enrollees. We estimate a one-time state burden of 6 hr at $53.32/hr for a business operations specialist to develop these definitions. In aggregate, we estimate 198 hr (33 states × 6 hr) and $10,557.36 (198 hr × $53.32/hr).

Section 438.10(c)(4)(ii) would recommend that states create model enrollee handbooks and notices. Since many states already provide model handbooks and notices to their entities, we estimate that 15 states may need to take action to comply with this provision. We estimate a one-time state burden of 40 hr at $53.32/hr for a business operations specialist to create these documents. In aggregate, we estimate 600 hr (15 states × 40 hr) and $31,992.00 (600 hr × $53.32/hr). We also estimate an annual state burden of 2 hr at $53.32/hr for a business operations specialist to maintain these documents. In aggregate, we estimate 30 hr (15 states

× 2 hr) and $1,599.60 (30 hr × $53.32/hr).

Section 438.10(d)(1) would require that states identify prevalent non-English languages spoken in each managed care entity's service area. Given that states must already determine the prevalent non-English languages spoken in their entire Medicaid service area based on the policy guidance ''Enforcement of Title VI of the Civil Rights Act of 1964—National Origin Discrimination Against Persons With Limited English Proficiency'' from the U.S. Department of Justice, we believe that dividing the information by plan service area requires only minimal IT programming. More specifically, we estimate a one-time state burden of 4 hr at $73.60/hr for a computer programmer to create these reports. In aggregate, we estimate 132 hr (33 states × 4 hr) and $9,715.20 (132 hr × $73.60/hr) to create these reports. We estimate no additional burden for the running of these reports as they would be put into a production schedule, and putting a report into production adds no additional burden.

Section 438.10(d)(2)(i) would require that states add taglines to all printed materials for potential enrollees explaining the availability of translation and interpreter services as well as the phone number for choice counseling assistance. We estimate a one-time state burden of 2 hr at $53.32/hr for a business operations specialist to create the taglines and another 4 hr to revise all document originals. In aggregate, we estimate 198 hr (33 states × 6 hr) and $10,557.36 (198 hr × $53.32/hr). As the prevalent languages within a state do not change frequently, we are not estimating burden for the rare updates that would be needed to these taglines.

Section 438.10(e)(1) would clarify that states can provide required information in paper or electronic format. As the amount and type of information that can be provided electronically will vary greatly among the states due to enrollee access and knowledge of electronic communication methods, it is not possible to estimate with any accuracy the amount that will be able to be converted from written to electronic format. Therefore, we will use estimates for all written materials knowing that some of this burden will be alleviated as the states are gradually able to convert to electronic communication methods. In this regard, we estimate a one-time state burden of 40 hr at $53.32/hr for a business operations specialist to create the materials. Many states already provide similar information to potential enrollees, so we anticipate that only 15 states would need to create these materials. We also estimate 1 min at $29.92/hr for an office and administrative support worker to mail the materials annually. For existing states, we estimate 1 hr at $53.32/hr for a business operations specialist to update or revise existing materials and 1 min at $29.92/hr for a mail clerk to mail the materials to 5 percent of the enrollees that are new (306,937 enrollees). In aggregate, we estimate a one-time state burden of 600 hr (15 states × 40 hr) and $31,992 (600 hr × $53.32/hr) to create materials. We estimate a one-time state burden of 33 hr (33 states × 1 hr) and $1,759.56 (33 hr × $53.32/hr) to update or revise existing materials. The state will also need to mail the materials. We estimate an ongoing burden of 5,115.6 hr (306,937 enrollees × 1 min) and $153,058.75 (5,115.6 hr × $29.92/hr) to mail materials.

Although § 438.10(g)(1) and (2) would require the provision of an enrollee handbook, Medicaid regulations have always required the provision of this information (although it did not specifically call it a ''handbook'') so we do not anticipate that all entities would need to create a new handbook. Additionally, given the requirement in § 438.10(c)(4)(ii) (which would be adopted in CHIP through § 457.1207) for the state to provide a model template for the handbook, the burden on an entity is greatly reduced. We estimate approximately 5 new managed care entities per year using 10 hr at $53.32/hr for a business operations specialist to create a handbook using their state's model template. In aggregate, we estimate 50 hr (5 entities × 10 hr) and $2,666 (50 hr × $53.32/hr). For existing MCOs, PIHPs, PAHPs, and PCCMs that already have a method for distributing the information, we believe that 20 entities will need to modify their existing handbook to comply with a new model provided by the state. We also estimate a one-time private sector burden of 4 hr at $53.32/hr for a business operations specialist to update their entity's handbook. Once revised, we estimate 1 min at $29.92/hr for an office and administrative support worker to send these handbooks to 3,069,371 enrollees (50 percent of total enrollment). In aggregate, we estimate 80 hr (20 entities × 4 hr) and $4,265.60 (80 hr × $53.32/hr) to update handbooks. To send the updated handbooks, we estimate 51,156.2 hr (3,069,371 enrollees × 1 min) and $1,530,593.50 (51,156.2 hr × $29.92/hr).

All new enrollees must receive a handbook within a reasonable time after receiving notice of the beneficiary's enrollment. We assume a 5 percent enrollee growth rate thus 306,937 enrollees (5 percent of 6,138,743) would need to receive a handbook each year. (Existing enrollees typically do not receive a new handbook annually unless significant changes have occurred so this estimate is for new beneficiaries only.) We estimate a private sector state burden of 1 min at $29.92/hr for an office and administrative support worker to mail the handbook. In aggregate, we estimate 5,115.6 hr (306,937 enrollees × 1 min) and $153,058.75 (5,115.6 hr × $29.92/hr) to send handbooks to new enrollees.

All entities would need to keep their handbook up to date. In this regard, we estimate an annual private sector burden of 1 hr at $53.32/hr for a business operations specialist to update the handbook. While the updates would need to be made as program changes occur, we estimate 1 hr since each change may only take a few minutes to make. In aggregate, we estimate 66 hr (66 entities × 1 hr) and $3,519.12 (66 hr × $53.32/hr).

Section 438.10(h) would require that MCOs, PIHPs, PAHPs, and PCCMs make a provider directory available in paper or electronic form. Producing a provider directory is a longstanding Medicaid requirement in § 438.10 as well in the commercial health insurance market. Additionally, given the time sensitive nature of provider information and the notorious high error rate in printed directories, most provider information is now obtained via Web site or by calling the customer service unit. Thus, the only new burden estimated would be the time for a computer programmer to add a few additional fields of data as appropriate, specifically, provider Web site addresses, additional disability accommodations, and adding behavioral and long-term services and support providers. We estimate a one-time private sector burden of 1 hr at $73.60/hr for a computer programmer to update the existing directory. In aggregate, we estimate 66 hr (66 entities × 1 hr) and $4,858 (66 hr × $73.60/hr). Updates after creation of the original program would be put on a production schedule, which generates no additional burden.

45. ICRs Regarding Requirements That Apply to MCO, PIHP, PAHP, and PCCM Contracts Involving Indians, Indian Health Care Providers, and Indian Managed Care Entities (§ 457.1208)

Section 457.1208 would apply the requirements of § 438.14 to CHIP. Section 438.14(c) would require states to make supplemental payments to Indian providers if the managed care entity does not pay at least the amount paid to Indian providers under the FFS

program. There are approximately 25 states with separate CHIPs that have federally recognized tribes. We do not know how many managed care entities have Indian providers, but estimate that it is approximately 40 entities. This type of payment arrangement typically involves the managed care entity sending a report to the state, which then calculates and pays the amount owed to the Indian health care provider. We estimate it would take 1 hr at $73.60/hr for a computer programmer to create the claims report and approximately 12 hr at $53.32/hr for a state business operations specialist to process the payments. We estimate that approximately 25 states will need to use this type of arrangement. In aggregate, we estimate a one-time private sector burden of 40 hr (40 entities × 1 hr) and $2,944.00 (40 hr × $73.60/hr). We also estimate an ongoing state burden of 300 hr (25 states × 12 hr) and $15,996.00 (300 hr × $53.32/hr).

After the MCO, PIHP, PAHP, and PCCM report is created, it will most likely run automatically at designated times and sent electronically to the state as the normal course of business operations; therefore, no additional burden is estimated after the first year.

(**Note:** this process is not necessary when the MCO, PIHP, PAHP, or PCCM entity pays the ICHP at least the full amount owed under this regulation.)

46. ICRs Regarding Managed Care Enrollment (§ 457.1210)

Section 457.1210(a) would require state to establish a process for prioritizing individuals for enrollment into managed care plans. Establishing a default enrollment process would require policy changes and require the state to send notices to enrollees once they have been enrolled in a plan. We estimate that states would need to use the default enrollment process specified in § 457.1210(a) for 5 percent of enrollees (306,937), and that it would take 1 min at $29.92/hr for a mail clerk to send the notice. In aggregate, we estimate 5,115.6 hr (306,937 beneficiaries × 1 min) and $153,059.25 (5,115.6 hr × $29.92/hr) to send the notices.

47. ICRs Regarding Disenrollment (§ 457.1212)

Section 457.1212 would apply the requirements of § 438.56 to CHIP. To disenroll, § 438.56(d)(1) would require that the beneficiary (or his or her representative) submit an oral or written request to the state agency (or its agent) or to the MCO, PIHP, PAHP, or PCCM, where permitted. We estimate that 5 percent of MCO, PIHP, PAHP, and PCCM enrollees will request that they be disenrolled from an MCO, PIHP, PAHP, or PCCM each year. We also estimate approximately one-fourth of the enrollees will choose a written rather than an oral request.

We estimate an ongoing burden of 10 min for an enrollee to generate a written disenrollment request and 3 min per oral request. In aggregate, we estimate an annual burden (written requests) of 12,789 hr (76,734 enrollees × 10 min) and 11,510.1 hr (230,202 enrollees × 3 min) for oral requests.

48. ICRs Regarding Conflict of Interest Safeguards (§ 457.1214)

Section 457.1214 would apply the requirements of § 438.58 to CHIP. Section 438.58 would require that states have in place safeguards against conflict of interest for employees or agents of the state who have responsibilities relating to the MCO, PIHP, or PAHP. We anticipate that most states already have such safeguards in place, and only 5 states would need to develop new standards to comply with this provision. We estimate a one-time state burden of 10 hr at $53.32/hr for a business operations specialist to develop those standards. In aggregate, we estimate 50 hr (5 states × 10 hr) and $2,666.00 (50 hr × $53.32/hr).

49. ICRs Regarding Continued Services to Beneficiaries (§ 457.1216)

Section 457.1216 would apply the requirements of § 438.62 to CHIP. Section 438.62(b)(1) would require that states have a transition of care policy for all beneficiaries moving from FFS CHIP into a MCO, PIHP, PAHP or PCCM, or when an enrollee is moving from one MCO, PIHP, PAHP, or PCCM to another and that enrollee would experience a serious detriment to health or be at risk of hospitalization or institutionalization without continued access to services. We estimate a one-time state burden of 10 hr at $53.32/hr for a business operations specialist to develop the transition of care policy. In aggregate, we estimate 330 hr (33 states × 10 hr) and $17,595.60 (330 hr × $53.32/hr).

Section 438.62(b)(2) would require that MCOs, PIHPs, PAHPs, or PCCMs implement their own transition of care policy that meets the requirements of § 438.62(b)(1). We estimate it would take 4 hr at $73.60/hr for a computer programmer to create the program that gathers and sends the FFS data to the MCOs, PIHPs, PAHPs, or PCCMs. We also estimate each MCO, PIHP, PAHP, or PCCM will use 4 hr of a computer programmer time to create programs to receive and store data as well as gather and send data to other plans. We are not estimating additional burden for the routine running of these reports as they will be put into a production schedule. In aggregate, we estimate a one-time state burden of 132 hr (33 states × 4 hr) and $9,715.20 (132 hr × $73.60/hr) to create the program that gathers and sends the FFS data to the MCOs, PIHPs, PAHPs, or PCCMs. We also estimate a one-time private sector burden of 264 hr (66 MCOs, PIHPs, PAHPs, or PCCMs × 4 hr) and $19,430.40 (264 hr × $73.60/hr) to create programs to receive and store data as well as gather and send data to other plans.

Once a MCO, PIHP, PAHP, or PCCM receives a request or identifies a need to arrange for the transition of services, we estimate a registered nurse at the managed care plan may need 10 min, on average, to access the stored information and take appropriate action. We believe that an average of 25,000 beneficiaries will transition into managed care each year from FFS and 5,000 may switch between plans that would meet the state defined standards to qualify for the transition of care policy. In aggregate, we estimate an annual for private sector burden of 5,000 hr (30,000 beneficiaries × 10 min) and $327,000.00 (5,000 hr × $65.40/hr).

50. ICRs Regarding Network Adequacy Standards (§ 457.1218)

Section 457.1218 would apply the requirements of § 438.68 to CHIP. Section 438.68(a) would require that states set network adequacy standards that each MCO, PIHP and PAHP must follow. Section 438.68(b) and (c) would require that states set standards that must include time and distance standards for specific provider types and network standards for LTSS (if the MCO, PIHP or PAHP has those benefits covered through their contract).

We believe some states already comply with these requirements and that only 12 states would need to develop the standards. We estimate a one-time first year burden of 15 hr at $53.32/hr for a business operations specialist to develop network standards meeting the specific provider types found in § 438.68(b)(1). In aggregate, we estimate 180 hr (12 states × 15 hr) and $9,597.60 (180 hr × $53.32/hr).

Very few states include LTSS in CHIP, therefore we estimate only 5 states will need to develop related standards. We estimate a one-time burden of 10 additional hr at $53.32/hr for a business operations specialist to develop those standards. In aggregate, we estimate 50 hr (5 states × 10 hr) and $2,666.00 (50 hr × $53.32/hr) for the development of LTSS standards. After network standards are established, we estimate

that the maintenance of the network standards will be part of usual and customary business practices and therefore, we do not estimate any burden for states after the first year.

Section 438.68(d) would require that states: (1) develop an exceptions process for plans unable to meet the state's standards; and (2) review network performance for any MCO, PIHP or PAHP to which the state provides an exception. We estimate a one-time state burden of 3 hr at $53.32/hr for a business operations specialist to establish an exceptions process. In aggregate, we estimate 99 hr (33 states × 3 hr) and $5,278.68 (99 hr × $53.32/hr).

The exception process should not be used very often as MCOs, PIHPs, and PAHPs meeting the established standards is critical to enrollee access to care. As such, after the exceptions process is established, we estimate that the occasional use of it will not generate any measurable burden after the first year.

51. ICRs Regarding Enrollee Rights (§ 457.1220)

Section 457.1220 would apply the requirements of § 438.100 to CHIP. We do not anticipate a burden associated with implementing this section, because the proposed requirements to provide enrollees with treatment options and alternatives, allow enrollees to participate in decisions regarding health care, ensure that enrollees are free from restraint or seclusion, are standard practice in the field. The burden associated with providing information in accordance with 45 CFR 164.524 and 164.526 is accounted for in the collection of information associated with those regulations. The burden associated with modifying contracts to comply with this regulation are accounted for under § 457.1202.

52. ICRs Regarding Provider-Enrollee Communication (§ 457.1222)

Section 457.1222 would apply the requirements of § 438.102 to CHIP. Section 438.102(a)(2) provides that MCOs, PIHPs, and PAHPs are not required to cover, furnish, or pay for a particular counseling or referral service if the MCO, PIHP, or PAHP objects to the provision of that service on moral or religious grounds and that written information on these policies is available to: (1) Prospective enrollees, before and during enrollment; and (2) current enrollees, within 90 days after adopting the policy for an any particular service.

We believe the burden for providing written notice to current enrollees within 90 days of adopting the policy for a specific service, would affect no more than 3 MCOs or PIHPs annually since it would apply only to the services they discontinue providing on moral or religious grounds during the contract period. PAHPs are excluded from this estimate because they generally do not provide services that would be affected by this provision.

We estimate that each of the 3 MCOs or PIHPs would have such a policy change only once annually. We estimate that it would take 1 hr at $53.32/hr for a business operations analyst to update the policies. In aggregate, we estimate 3 hr (3 MCOs/PIHPs × 1 hr) and $159.96 (3 hr × $53.32/hr). We further estimate that it would take 4 hr at $53.32/hr for a business operations specialist to create the notice and 1 min at $29.92/hr for an office and administrative support worker to mail each notice. With an average MCO/PIHP enrollment of 78,000 enrollees, we estimate a total annual burden of 12 hr (3 MCOs/PIHPs × 4 hr/notice) and $639.84 (12 hr × $53.32/hr) to create the notice. To mail the notice we estimate 3,900 hr (3 MCOs/PIHPs × 78,000 enrollees × 1 min/notice) and $116,688 (3,900 hr × $29.92/hr).

53. ICRs Regarding Marketing Activities (§ 457.1224)

Section 457.1224 would apply the requirements of § 438.104 to CHIP. Section 438.104(c) would require that the state review marketing materials submitted by managed care entities. We believe that each entity would revise its materials once every 3 years. We estimate a state burden of 3 hr at $53.32/hr for a business operations specialist to review an entity's materials. In aggregate, we estimate an annual state burden of 75 hr [3 hr × 25 entities (one third of the total entities)] and $3,999 (75 hr × $53.32/hr).

We estimate that 5 entities may need to revise and submit updated materials. We estimate a private sector burden of 2 hr at $53.32/hr for a business operations specialist to update and submit the materials. In aggregate, we estimate a one-time burden of 10 hr (5 entities × 2 hr) and $533.20 (10 hr × $53.32).

54. ICRs Regarding Access Standards (§ 457.1230)

Section 457.1230 would apply the requirements of §§ 438.206, 438.207, 438.208, and 438.210 to CHIP. Section 438.206(c)(3) through 457.1230(a), would require that MCOs, PIHPs, and PAHPs ensure that providers assure access, accommodations, and equipment for enrollees with physical and/or mental disabilities. We believe that MCOs, PIHPs, and PAHPs will need to review and revise (possibly) their policies and procedures for network management to ensure compliance with this requirement.

We estimate a one-time private sector burden of 3 hr at $53.32/hr for a business operations specialist to review and revise their network management policies and procedures. In aggregate, we estimate 189 hr (63 MCO/PIHP/PAHPs × 3 hr) and $10,077.48 (189 hr × $53.32/hr).

Section 438.207(b) through 457.1230(b) and 438.207(b) would require that each MCO, PIHP, and PAHP (where applicable) submit documentation to the state, in a format specified by the state, to demonstrate that it: (1) Complies with specified requirements, and (2) has the capacity to serve the expected enrollment in its service area in accordance with the state's standards for access to care. Section 438.207(c) would require that the documentation be submitted to the state at least annually, at the time the MCO, PIHP, or PAHP enters into a contract with the state, and at any time there has been a significant change (as defined both by the state) in the MCO, PIHP, or PAHP's operations that would affect adequate capacity and services.

We estimate an annual private sector burden of 20 hr at $53.32/hr for a business operations specialist to compile the information necessary to meet this requirement. In aggregate, we estimate 1,260 hr (63 entities × 20 hr) and $67,183.20 (1,260 hr × $53.32/hr).

After reviewing the documentation, § 438.207(d) through 457.1230(a), would require that the state certify (to CMS) that the entity has complied with the state's requirements regarding the availability of services, as set forth at § 438.68. We estimate an annual state burden of 1 hr/contract at $53.32/hr for a business operations specialist to review documentation and submit the certification to CMS. In aggregate, we estimate 63 hr (63 entities × 1 hr) and $3,359.16 (63 hr × $53.32/hr).

Section 438.208(b)(2)(iii) through 457.1230(c), would require that MCOs, PIHPs and PAHPs coordinate service delivery with the services the enrollee receives in the FFS program (carved out services). This would involve using data from the state to perform the needed coordination activities. Since only a small percentage of enrollees receive carved out services and need assistance with coordination, we estimate 2 percent of all MCO, PIHP, and PAHP enrollees (122,775) will be affected.

We estimate an annual private sector burden of 10 min/enrollee at $59.20/hr for a healthcare social worker. In

aggregate, we estimate 20,463hr (122,775 enrollees × 10 min) and $1,211,380.00(20,463 hr × $59.20/hr).

Section 438.208(b)(3) through 457.1230(c), would require that an MCO, PIHP or PAHP make its best effort to conduct an initial assessment of each new enrollee's needs within 90 days of the enrollment. We believe that most MCOs and PIHPs already meet this requirement and only 25 percent of the MCOs and PIHPs (15) would need to alter their processes; however, we do not believe this to be as common a practice among PAHPs and assume that all 3 PAHPs will be need to add this assessment to their initial enrollment functions.

We estimate a one-time private sector burden of 3 hr at $53.32/hr for a business operations specialist to revise their policies and procedures. In aggregate, we estimate 54 hr [(15 MCOs and PIHPs + 3 PAHPs) × 3 hr] and $2,879.28 (54 hr × $53.32/hr).

We estimate that in a given year, approximately 10 percent of all enrollees are new to a managed care plan. Thus, 613,874 enrollees would be considered new and in need of an initial assessment. As PAHPs are typically a single entity within the state, we will only estimate that 5 percent of their enrollees (10,000 enrollees) would need an initial assessment. In general, we believe these assessments will take 10 min on average to complete by Call Center staff at $29.92/hr. In aggregate, we estimate an annual private sector burden of 102,312.33 hr (613,874 enrollees × 10 min) and $3,061,185.01 (102,312.33 hr × $29.92/hr).

Section 438.208(b)(4) through 457.1230(c), would require that MCOs, PIHPs, and PAHPs share with other MCOs, PIHPs, and PAHPs serving the enrollee the results of its identification and assessment of any enrollee with special health care needs so that those activities need not be duplicated. The burden associated with this requirement is the time it takes each MCO, PIHP or PAHP to disclose information on enrollees with special health care needs to the MCO, PIHP or PAHP providing a carved out service. This would most likely be accomplished by developing a report to collect the data and sending that report to the other MCO, PIHP, or PAHP.

We estimate a one-time private sector burden of 4 hr at $73.60/hr for a computer programmer to develop the report. In aggregate, we estimate of 252 hr (63 MCOs, PIHP, and PAHPs × 4 hr) and $18,547.20 (288 hr × $73.60/hr). Once put into production on a schedule, no additional staff time would be needed, thus no additional burden is estimated.

Section 438.208(c)(2) and (3) through 457.1230(c), would require that the MCOs, PIHPs and PAHPs complete a comprehensive assessment and treatment plan for all enrollees that have special health care needs. The assessments and treatment plans should be completed by providers or MCO, PIHP or PAHP staff that meet the qualifications specified by the state. We believe the burden associated with this requirement is the time it takes to gather the information during the assessment. (Treatment plans are generally developed while the assessment occurs so we are not estimating any additional time beyond the time of the assessment.) We believe that only enrollees in MCOs and PIHPs will require this level of assessment as most PAHPs provide limited benefit packages that do not typically warrant a separate treatment plan.

We estimate that 1 percent of the total enrollment of 6,138,743 (61,387) are enrolled in either a MCO, PIHP or both, and would qualify as an individual with special health care needs. The time needed for the assessment and for treatment planning will, on average, take 1 hr at $65.40/hr for a registered nurse to complete. In aggregate, we estimate an annual private sector burden of 61,387 hr (61,387 enrollees × 1 hr) and $4,014,709.80 (61,387 hr × $65.40/hr).

Section 438.210(c) through 457.1230(d), would require that each contract provide that the MCO, PIHP, or PAHP notify the requesting provider, and give the enrollee written notice of any decision by the MCO, PIHP, or PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested.

We estimate an annual private sector burden of 30 min at $65.40/hr for a registered nurse to generate the notice. We estimate that each of 63 MCOs, PIHPs and PAHPs would process 20 denials/service reductions per 1,000 members. With average enrollment of 78,000, each entity is estimated to process a total of 1,560 denials and service reductions annually. In aggregate, we estimate 49,140 hr (63 entities × 1,560 denials or service reductions/entity × 30 min) and $3,213,756.00 (49,140 hr × $65.40/hr).

55. ICRs Regarding Structure and Operation Standards (§ 457.1233)

Section 457.1233 would apply the requirements of §§ 438.214, 438.230, 438.236, and 438.242 to CHIP. Section 438.214 would require that MCOs, PIHPs, and PAHPs have policies for the selection and retention of providers. As described in section IV.B.55. of this proposed rule, we believe that the requirements in §§ 438.214 are part of the usual course of business and will not add additional burden onto entities because the entities will have policies for selecting and retaining providers even in the absence of these regulations.

Section 438.230 through § 457.1233(b), would require that MCOs, PIHPs, and PAHPs oversee subcontractors and would specify the subcontracted activities. We estimate 3 hr at $53.32/hr for a business operations analyst to amend appropriate contracts. We estimate a one-time private sector burden of 189 (63 MCOs, PIHPs, and PAHPs × 3 hr) and $10,077.48 (189 hr × $53.32). Section 438.236(c) through § 457.1233(c), would require that each MCO, PIHP, and PAHP disseminate guidelines to its affected providers and, upon request, to enrollees and potential enrollees. The burden associated with this requirement is the time required to disseminate the guidelines, usually by posting on their Web site. This is typically done annually. We estimate an annual private sector burden of 2 hr at $53.32/hr for a business operations specialist. In aggregate, we estimate 124 hr (62 entities × 2 hr) and $6,611.68 (124 hr × $53.32/hr).

In § 438.242(b)(2) through § 457.1233(b), the state would be required to stipulate that each MCO and PIHP collect data on enrollee and provider characteristics (as specified by the state) and on services furnished to enrollees (through an encounter data system or other such methods as may be specified by the state). We estimate a one-time private sector burden of 20 hr at $73.60/hr for a computer programmer to extract this data from an entity's system and report to the state. In aggregate, we estimate 1,180 hr (59 entities × 20 hr) and $86,848 (1,180 hr × $73.60/hr). After the initial creation, the reports would be set to run and sent to the state at specified times as part of a production schedule.

56. ICRs Regarding Quality Measurement and Improvement (§ 457.1240)

Section 457.1240 would apply the requirements of §§ 438.330, 438.332, 438.334, and 438.340 to CHIP. Section 438.330(a)(2) through § 457.1240(b), would authorize CMS to use a public notice and comment process to identify performance measures and PIP topics that states would include in their contracts with MCOs, PIHPs, and PAHPs. Should CMS use this process to identify specific performance measures

and PIP topics at least once every 3 years, we expect that states would need to program their MMIS systems to account for the specified performance measures and PIP topics. We estimate that MMIS programming changes would require 10 hr (every 3 years) at $73.60/hr for a computer programmer. In aggregate, we estimate an ongoing annualized state burden of 110 hr [(33 states × 10 hr)/3 years] and $8,096 (110 hr × $73.60/hr).

Section 438.330(a)(2)(i) through § 457.1240(b), allows states to select performance measures and performance improvement projects (PIPs) in addition to those specified by CMS under § 438.330(a)(2). Since this language continues the flexibility available to states today, we do not believe this creates any change in burden for states or the private sector.

Section 438.330(a)(2)(ii) allows states to apply for an exemption from the CMS-required performance measure and PIP topic requirements established under § 438.330(a)(2). While we have no data on how many states would take advantage of this option, given that the performance measures and PIP topics under § 438.330(a)(2) would be identified through a public notice and comment process, we estimate that 2 states would ask for an exemption every 3 years. We estimate that the exemption process would require 1 hr at $53.32/hr for a business operations specialist. In aggregate, we estimate an ongoing annualized state burden of 0.67 hr [(2 states × 1 hr)/3 years] and $36.72 (0.67 hr × $53.32/hr).

Section 438.330(b)(3) would clarify that MCOs, PIHPs, and PAHPs must have an approach to evaluate and address findings regarding the underutilization and overutilization of services. Because utilization review in managed care has become commonplace in the commercial, Medicare, and Medicaid settings, we do not believe that this regulatory provision imposes any new burden on MCOs, PIHPs, or PAHPs.

In accordance with § 438.310(c)(2), some PCCM entities (we estimate 3) will now be subject to the requirements of § 438.330(b)(3). We estimate a one-time private sector burden of 10 hr at $53.32/hr for a business operations specialist to establish the policies and procedures. In aggregate, we estimate 30 hr (3 PCCMs × 10 hr) and $1,599.60 (30 hr × $53.32/hr). We also estimate an ongoing burden of 10 hr to evaluate and address the findings. In aggregate, we estimate an annual burden of 30 hr (3 PCCMs × 10 hr) and $1,599.60 (30 hr × $53.32/hr) for program maintenance.

Section 438.330(c)(1) through (3) through § 457.1240(b), would require that each MCO, PIHP, and PAHP annually measure its performance using standard measures required by the state and report its performance to the state. Because the use of performance measures in managed care has become commonplace in commercial, Medicare, and Medicaid managed care, we do not believe that this regulatory provision imposes any new burden on MCOs, PIHPs, or states.

In accordance with § 438.310(c)(2) through § 457.1240(b), some PCCM entities will now be subject to this requirement. We recognize that PAHPs and PCCM entities may not currently engage in performance measurement, and estimate that 7 entities might be impacted. We estimate that, in any given year, each PCCM entity and each PAHP would report to the state on at least 3 performance measures. We estimate an annual private sector burden of 4 hr per measure at $53.32/hr for a business operations specialist to prepare a report for each performance measure. In aggregate, we estimate 84 hr [(3 PAHPs + 4 PCCMs) × 3 performance measures × 4 hr] and $4,478.88 (84 hr × $53.32/hr).

In § 438.330(d)(1) through § 457.1240(b), states would ensure that each MCO, PIHP and PAHP have an ongoing program of performance improvement projects (PIPs). In § 438.330(d)(2) each MCO, PIHP, and PAHP would be required to report the status and results of each such project to the state, as requested. We estimate that, in any given year, each of the 59 MCOs and PIHPs would conduct at least 3 PIPs and each of the 4 PAHPs would conduct at least 1 PAHP. We further expect that states will request the status and results of each entity's PIPs annually. Given that PAHPs may not currently conduct PIPs, we estimate a one-time private sector burden of 2 hr at $53.32/hr for a business operations specialist to develop policies and procedures, for an aggregate burden of 8 hr (4 PAHPs × 2 hr) and $426.56 (8 hr × $53.32/hr). We estimate an annual burden of 8 hr to prepare a report on each PIP. In aggregate, we estimate 1,448 hr [((59 MCOs and PIHPs × 3 PIPs) + (4 PAHPs × 1 PIP)) × 8 hr] and $77,207.36 (1,448 hr × $53.32/hr) to prepare the report.

Per § 438.310(c)(2), PCCM entities specified are also subject to the requirements in § 438.330(e) through § 457.1240(b). We estimate an annual state burden of 15 hr at $53.32/hr for a business operations specialist to assess the performance of a single § 438.3(r) PCCM entity. In aggregate, we estimate 45 hours (3 PCCM entities × 15 hr) and $2,399.40 (45 hr × $53.32/hr).

Section 438.330(e)(1)(ii) through § 457.1240(b), would require that states include outcomes and trended results of each MCO, PIHP, and PAHP's PIPs in the state's annual review of quality assessment and performance improvement programs. We estimate a one-time state burden of 0.5 hr at $53.32/hr for a business operations specialist to modify the state's policies and procedures. In aggregate, we estimate 16.5 hr (33 states × 0.5 hr) and $879.78 (16.5 hr × $53.32/hr). We also estimate an annual burden of 1 hr for the additional review. In aggregate, we estimate 33 hr (33 states × 1 hr) and $1,759.56 (33 hr × $53.32/hr). Section 438.330(e)(1)(iii) would set out a new requirement, related to § 438.330(b)(5), requiring that the state must assess the rebalancing effort results for LTSS in its annual review. We do not know of any states that have an LTSS plan in CHIP, so there is no burden associated with the proposed provision.

Under § 438.332(a) through § 457.1240(c), states would review and approve the performance of all CHIP MCO, PIHP, and PAHP at least once every 3 years. We assume that no state would set up a separate review and approval process for CHIP, and would instead follow the same process used for Medicaid managed care plans. We estimate an annual state burden of 80 hr at $53.32/hr for a business operations specialist, 5 hr at $127.72/hr for a general and operations manager, and 5 hr at $29.92/hr for an office and administrative support worker to assess a CHIP plan, which would occur at least once every 3 years. In aggregate, we estimate an annualized state burden of 1,980 hr (66 MCOs, PIHPs, and PAHPs × 90 hr/3 years) and $157,594.80 [(66 MCOs, PIHPs, and PAHPs × [(80 hr × $53.32/hr) + (5 hr × $127.72/hr) + (5 hr × $29.92/hr)])/3 years] to review and approve CHIP MCOs, PIHPs, and PAHPs. We estimate an annualized private sector burden of 1,078 hr [(66 MCOs, PIHPs, and PAHPs × 49 hr/3 years) and $61,452.16 [(66 MCOs, PIHPs, and PAHPs × [(40 hr × $53.32/hr) + (5 hr × $29.92/hr) + (4 hr × $127.72/hr)])/3 years] for CHIP MCOs, PIHPs, and PAHPs to provide the necessary information to the state for review and approval.

Section 438.332(b)(2) through § 457.1240(c), would allow states to deem compliance with § 438.332(a) for accredited MCOs, PIHPs, and PAHPs that authorize the private accrediting entity to release accreditation information to the state. The burden associated with operating this program

at a state is captured in § 438.332(b), were we assume that half of states will elect this option. We believe that approximately half of the CHIP MCOs, PIHPs, and PAHPs (17) in these states may already have received or are independently seeking accreditation, and thus would not face any additional burden associated with this requirement. The remaining 16 MCOs, PIHPs, and PAHPs (half the entities in half the states) would have to seek initial accreditation from a private accrediting entity. The burden for accreditation varies widely, depending on a number of factors including the type of managed care entity, the size of its population, and the accrediting body. We estimate that initial accreditation costs $70,700 per plan (given that private independent entities structure prices in terms of accreditation activities, not hours, an hourly burden estimate is not available) and must be renewed once every 3 years for the same cost. In aggregate, we estimate the one-time private sector burden for initial accreditation is $1,131,200 (16 MCOs, PIHPs, and PAHPs × $70,700), and the ongoing annualized private sector burden for accreditation renewal is $377,066.67 [(16 MCOs, PIHPs, and PAHPs × $70,700)/3 years].

Section 438.332(c) through § 457.1240(c), requires the state to document its determinations for all MCOs, PIHPs, and PAHPs on the state's Web site, the burden for which is included in § 438.10.

Section 438.334 through § 457.1240(d), would have states establish and operate a quality ratings system for MCOs, PIHPs, and PAHPs. We assume that states would utilize the same system and processes developed for CHIP managed care plans as was developed for Medicaid managed care plans. Using the assumptions developed for § 438.332, we estimate that 25 states (with 47 MCOs, PIHPs, and PAHPs) will operate a quality rating systems as proposed in § 438.334(a) and would rate plans each year. We estimate 20 hr at $53.32/hr for a business operations specialist in a state to rate a MCO, PIHP, or PAHP. In aggregate, we estimate an annual state burden of 940 hr (47 MCOs, PIHPs, and PAHPs × 20 hr) and $50,120.80 (940 hr × $53.32/hr). We assume the remaining 8 states (with 16 MCOs, PIHPs, and PAHPs) will utilize the flexibility at § 438.334(c) to continue to use their own quality rating system. As this would not be a change from the status quo, we estimate no additional burden in these states for the quality rating system.

Section 438.340 through § 457.1240(e), would describe the additional comprehensive quality strategy elements that states contracting with MCOs, PIHPs, or PAHPs would include in their comprehensive quality strategies. To include the additional managed care-related items in their comprehensive quality strategies, we estimate a state burden of 10 hr at $53.32/hr for a business operations specialist each time a state revises its comprehensive quality strategy (once every 3 years, per § 431.504(b)). In aggregate, we estimate an annualized burden of 110 hr [(33 states × 10 hr)/3 years] and $5,865.20 (110 hr × $53.32/hr).

57. ICRs Regarding External Quality Review (§ 457.1250)

Section 457.1250 would apply the requirements of §§ 438.350, 438.352, 438.354, 438.356, 438.358, and 438.364 to CHIP. Section 438.350 through § 457.1250(a), would require that states include CHIP in their external quality review. We anticipate that most states would include CHIP in their Medicaid contract with the EQRO and that the burden for adding CHIP would be included in the burden for adding PAHPs to the EQRO contract. We anticipate that 5 states may contract separately for CHIP EQR services and that this would require states to procure a new vendor.

Given the wide variance in state procurement processes, the burden is conservatively estimated at 185 hr for writing an RFP, evaluating proposals, and implementing the selected proposal. More specifically, we estimate a one-time state burden of 125 hr at $53.32/hr for a business operations specialist, 50 hr at $73.60/hr for a computer programmer, and 10 hr at $127.72/hr for a general and operations manager. In aggregate, we estimate 925 hr [(125 hr + 50 hr + 10 hr) × 5 states] and $58,111.00 [((125 hr × $53.32/hr) + (50 hr × $$73.60/hr) + (10 hr × $127.72/hr) × 5 states)].

Section 438.356(a)(3) through § 457.1250(a), would require that states submit their EQRO contracts to CMS for review and approval prior to implementation. We estimate a one-time state burden of 2 hr at $53.32/hr for a business operations specialist to submit the contract to CMS. In aggregate, we estimate 10 hr (5 states × 2 hr) and $533.20 (10 hr × $53.32/hr).

Section 438.358 through § 457.1250(a), would require that the EQRO perform certain activities. The burden associated with this provision is the time for a state to conduct and document the findings of the four mandatory activities: (1) The annual validation of performance improvement projects conducted by the MCO/PIHP/PAHP; (2) the annual validation of performance measures calculated by the MCO/PIHP/PAHP; (3) once every 3 years, a review of MCO/PIHP/PAHP compliance with structural and operational standards; and (4) validation of MCO, PIHP, and PAHP network adequacy. Each of these activities would be conducted on the 5 MCOs/PIHPs/PAHPs that are currently providing CHIP services separately from Medicaid. The types of services provided by these managed care entities, the number of performance improvement projects conducted, and the performance measures calculated will vary. We assume that each MCO/PIHP will conduct at least 3 performance improvement projects, each PAHP will conduct at least 1 performance improvement project, and that each MCO/PIHP/PAHP will calculate at least 3 performance measures.

For a business operations specialist to conduct the mandatory EQR activities at $53.32/hr, we estimate an annual state burden of 65 hr (performance improvement project validation), 53 hr (performance measure validation), 361 hr (compliance review; occurs once every 3 years), and 60 hr (validation of network adequacy activity). In aggregate, we estimate 2,671.67hr (5 × [(65 hr × 3 performance improvement projects) + (53 hr × 3 performance measures) + (361 hr/3) + 60 hr]) and $142,453.27 (2,372 hr × $53.32/hr).

In § 438.358(b), the burden would include the time for an MCO/PIHP/PAHP to prepare the information necessary for the state to conduct the three mandatory activities. We estimate that it will take each MCO/PIHP/PAHP 160 hr to prepare the documentation for these activities. We estimate that one-half of the time would be for preparing the information which will be performed by a business operations specialist at $53.32/hr while the other half will be performed by office and administrative support worker at $29.92/hr. In aggregate, we estimate a private sector burden of 800 hr (5 states × 160 hr) and $33,296.00 [(5 states × 80 hr × $53.32/hr) + (5 states × 80 hr × $29.92/hr).

Section 438.358(b)(1) through § 457.1250(a), would stipulate that all of the PIPs required by the state and CMS be validated. We have added the reference to CMS-required PIPs to be consistent with our proposed provision at § 438.330(a)(3). While current regulations do not specify the number of PIPs that must be validated in each state, the majority of states validate multiple PIPs for each MCO or PIHP.

Given current practice, we do not anticipate this will pose a burden on states or the private sector beyond the need to modify MCO, PIHP, PAHP, and EQRO contracts. We anticipate that most states would include CHIP in their Medicaid contract with the EQRO and that the burden for adding CHIP would be included in the burden under § 438.350. The burden associated with amending MCO/PIHP/PAHP contracts is captured in § 457.1202.

Section 438.358(c) through § 457.1250(a), describes optional EQR-related activities. For the optional EQR activities, we have no data to estimate how long it would take to conduct these activities. We, therefore, estimate that it will take 350 hr to validate client level data and 50 hr to validate consumer or provider surveys. We estimate it will take three times as long to calculate performance measures as it takes on average to validate (159 hr) and three times as long to conduct performance improvement projects and focused studies as it takes on average to validate performance improvement projects (195 hr). We also estimate that it will take three times as long to administer a consumer or provider survey than it takes to validate a survey (60 hr).

For a business operations specialist $53.32/hr, we estimate: (1) 16,800 hr (350 hr × 48 MCOs/PIHPs) and $895,776.00 (16,800 hr × $53.32/hr) to validate client level data; (2) 1500 hr (50 hr × 30 MCOs/PIHPs) and $79,980.00 (1500 hr × $53.32/hr) to validate consumer or provider surveys; (3) 3,180 hr (159 hr × 20 MCOs/PIHPs) and $169,557.60 (3,180 hr × $53.32/hr) to calculate performance measures; (4) 5,070 hr (195 hr × 26 MCOs/PIHPs) and $270,332.40 (5,070 hr × $53.32/hr) to conduct performance improvement projects; and (5) 8,268 hr (159 hr × 52 MCOs/PIHPs) and $440,849.76 (8,268 hr × $53.32/hr) to conduct focused studies. In aggregate, we estimate 34,818 hr and $1,856,495.76 for the optional EQR-related activities.

We do not have any data to estimate the amount of time to prepare data and information for the optional EQR activities for PAHPs. We also do not have data regarding how states will apply these optional activities to PAHPs. Therefore, at this time, we are unable to develop a burden estimate for optional EQR-related activities for PAHPs. We welcome comment to help us develop these estimates.

Section 438.364(a)(1) through § 457.1250(a), specifies that information regarding the EQR activities may include information obtained from Medicare or private accreditation reviews in accordance with § 438.360. Section 438.364(a)(1)(iii) would require that the EQR technical report include baseline and outcomes data regarding PIPs and performance measures. The burden of compiling this data for MCOs, PIHPs, and PAHPs is captured in § 438.358.

Section 438.364(b)(1) through § 457.1250(a), would clarify that the EQRO must produce and finalize the annual EQR-technical report and that states may not substantively revise the report without evidence of error or omission, or permission from CMS. The proposed April 30th deadline for the finalization and submission of EQR technical reports is consistent with existing Medicaid sub-regulatory guidance. In an effort to ensure that the EQR process offers states timely and valuable insight into the quality of their managed care programs, we propose that the annual EQR technical report must address data collected in the previous 15 months.

We do not anticipate that these changes will pose a burden on states or the private sector. The burden associated with changing contracts for those programs that contract with EQROs with Medicaid is included under § 438.364. States that contract with an EQRO separately for CHIP will include this requirement in the contract.

Section 438.364(b)(2) through § 457.1250(a), would require that each state agency provide copies of technical reports, upon request, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO/PIHP/PAHP, beneficiary advocacy groups, and members of the general public. States would also be required to make the most recent EQR technical report publicly available in a manner specified by CMS. This will likely be accomplished by posting to the state's Web site, the burden for which is included in § 457.1206. We believe that by making these reports available online, states would be able to significantly decrease the burden associated with responding to requests from the public for this information, as it will already be easily accessible. The burden associated with this requirement is the time for a state agency to disclose copies of a given technical report to interested parties.

We estimate an annual state burden of 5 min at $15/hr for office and administrative support worker to disclose the required information per request. We also estimate that each state will receive 5 requests per MCO/PIHP/PAHP per year. In aggregate, we estimate 26 hr (62 MCOs/PIHPs/PAHPs × 5 requests × 5 min) and $772.93 (26 hr × $29.92/hr).

58. ICRs Regarding Grievances (§ 457.1260)

Section 457.1260 would apply subpart F of part 438 to CHIP. We anticipate that most states currently follow the Medicaid grievance procedures, so we adopt the burden associated with the proposed changes to the Medicaid regulation.

Section 438.400(b) through § 457.1260, would update the definition of ''Action'' to ''Adverse benefit determination,'' clarify ''appeal'' and ''grievance,'' and add the definition of ''grievance system.'' We estimate a one-time state burden of 5 hr at $53.32/hr for a business operations specialist to amend all relevant documents to the new nomenclature and definitions. In aggregate, we estimate 165 hr (5 hr × 33 states) and $8,797.80 (165 hr × $53.32/hr).

Aligning the definition of ''adverse benefit determination'' to include medical necessity, appropriateness, health care setting, or effectiveness would require that plans provide additional hearing resources to actions previously not included. We estimate 3 hr at $53.32/hr for a business operations specialist and expect that each plan would provide 3 additional hearings per month (36 per year). In aggregate, we estimate an annual private sector burden of 6,696 hr (62 MCOS, PIHPS, and PAHPS × 36 hearings × 3 hr) and $357,030.72 (6,696 hr × $53.32/hr).

Section 438.402 through § 457.1260, would specify the general requirements associated with the grievance system. More specifically, § 438.402 would: (1) Require MCOs, PIHPs, and PAHPs to have a grievance system; (2) set out general requirements for the system; (3) establish filing requirements; and (4) provide that grievances and appeals may be filed either orally or in writing. The proposed provisions would apply to 62 entities. The burden for revising the contracts for these entities is included in § 457.1201.

With regard to setting up a grievance system, we estimate it would take 100 hr (10 hr at $127.72/hr for a general and operations manager, 75 hr at $53.32/hr for a business operations specialist, and 15 hr at $73.60/hr for a computer programmer) for each entity. We estimate that the entities would receive 400 grievances per month. We estimate it will take a business operations specialist 30 min to process and handle each grievance and adverse benefit determinations.

We estimate a one-time private sector burden of 6,200 hr and $395,572.40 [62 MCOs, PIHPs, and PAHPs × ((10 × $127.72/hr) + (75 × $53.32/hr) + (15 ×

$73.60/hr)). We also estimate an annual burden of 148,800 hr [62 PAHPs × 400 grievances/month × 12 months × (0.5 hr/grievance × 12 months)] and $7,934,016.00 (148,800 hr × $53.32/hr) for processing each grievance and adverse benefit determination.

Section 438.404(a) through § 457.1260, would add PAHPs as an entity that must give the enrollee timely written notice and would set forth the requirements of that notice. More specifically, the enrollee must be provided timely written notice if an MCO, PIHP, or PAHP intends to: (1) Deny, limit, reduce, or terminate a service; (2) deny payment; (3) deny the request of an enrollee in a rural area with one plan to go out of network to obtain a service; or (4) fails to furnish, arrange, provide, or pay for a service in a timely manner.

We estimate an annual private sector burden of 1 min at $29.92/hr for an office and administrative support worker to provide written notice of the MCO, PIHP, or PAHP's intended action. We estimate that 5 percent (306,937) of the approximately 6 million MCO, PIHP, or PAHP enrollees will receive one notice of intended action per year from their MCO, PIHP, or PAHP. In aggregate, we estimate 5,116 hr (306,937 × 1 min) and $153,059.25 (5,116 hr × $29.92/hr).

In § 438.416 through § 457.1260, the state must require that MCOs, PIHPs and PAHPs maintain records of grievances and appeals. We estimate that approximately 6,139 enrollees (1 percent) of the approximately 6 million MCO and PIHP enrollees file a grievance or appeal with their MCO or PIHP. We estimate an annual private sector burden of 1 min (per request) at $29.92/hr for an office and administrative support worker to record and track grievances. In aggregate, we estimate 102 hr (6,139 grievances × 1 min) and $3,061.31 (102 hr × $29.92/hr).

59. ICRs Regarding Sanctions (§ 457.1270)

Section 457.1270 would apply subpart I of part 438 to CHIP. In § 438.722(a) through § 457.1270, states would be provided the option to give MCO, PIHP, PAHP, or PCCM enrollees written notice of the state's intent to terminate its MCO, PIHP, PAHP, or PCCM contract. Notice may be provided after the state has notified the entity of its intention to terminate their contract.

States already have the authority to terminate MCO, PIHP, PAHP or PCCM contracts according to state law and have been providing written notice to the MCO, PIHP, PAHP or PCCM enrollees. While it is not possible to gather an exact figure, we estimate that 8 states may terminate 1 contract per year.

We estimate an annual state burden of 1 hr at $53.32/hr for a business operations specialist to prepare the notice to enrollees. In aggregate, we estimate 8 hr (1 hr × 8 states × 1 contract/yr.) and $426.56 (8 hr × $53.32/hr). We also estimate 1 hr at $53.32/hr for a business operations specialist to prepare the notice. In aggregate, we estimate an annual state burden of 8 hr (8 states × 1 hr) and $427 (8 hr × $53.32/hr). To send the notice, we estimate an average enrollment of 30,000 beneficiaries and 1 min (per beneficiary) at $26.40/hr for a mail clerk. In aggregate we estimate 500 hr (30,000 beneficiaries × 1 min) and $13,200.00 (500 hr × $26.40/hr).

Section 438.724 through § 457.1270, would require that the state give the CMS Regional Office written notice whenever it imposes or lifts a sanction. The notice must specify the affected MCO, PIHP, PAHP, or PCCM, the kind of sanction, and the reason for the state's decision to impose or lift a sanction.

We anticipate that no more than 15 states would impose or lift a sanction each year and that it would take 30 min at $53.32/hr for a business operations specialist to give the regional office notice. In aggregate, we estimate an annual burden of 7.5 hr (15 states × 30 min) and $400 (7.5 hr × $53.32/hr).

60. ICRs Regarding Conditions Necessary To Contract as an MCO, PIHP, or PAHP (§ 457.1280)

These requirements have not changed, they have been redesignated from another section of part 457, and so we do not estimate any additional burden.

61. ICRs Regarding Program Integrity Safeguards (§ 457.1285)

Section 457.1285 would apply most of subpart H of part 438 to CHIP. Section 438.602(a) through § 457.1285, would detail state responsibilities for monitoring MCO, PIHP, PAHP, PCCM or PCCM's compliance with other sections of part 438, screening and enrollment of providers, reviewing ownership and control information, performing periodic audits, investigating based on whistleblower information, and imposing sanctions as appropriate. States would need to revise their policies and implement these activities, as needed. Once the policies are revised, the continuing performance would be part of usual and customary business operations.

We estimate 50 hr at $53.32/hr for a business operations specialist to create and/or revise their policies for the above activities. In aggregate, we estimate a one-time state burden of 1,650 hr (33 states × 50 hr) and $87,978.00 (1,650 hr × $53.32/hr).

Section 438.602(b) through § 457.1285, would require states to screen and enrollee MCO, PIHP, PAHP, PCCM and PCCM entity providers in accordance with 42 CFR part 455, subparts B and E. States are already required to screen and enroll providers in both FFS and managed care in their CHIP programs through 42 CFR 457.990, so there is no additional burden associated with this requirement.

Section 438.602(e) through § 457.1285, would require states to conduct or contract for audits of MCO, PIHP, and PAHP encounter and financial data once every 3 years. Some states already use their EQRO to validate data. If they conduct this task at an appropriate frequency, it would incur no additional burden. We estimate 12 states already use their EQRO to validate their data, so only 21 states may need to take action to meet this requirement. The method selected by the state will determine the amount of burden incurred. We assume an equal distribution of states selecting each method, thus 7 states per method.

A state using EQRO to validate data on less than an appropriate frequency may need to amend their EQRO contract. In this case, we estimate 1 hr at $53.32/hr for a business operations specialist. In aggregate, we estimate a one-time state burden of 7 hr (7 states × 1 hr) and $373.24 (7 hr × $53.32/hr).

A state electing to perform validation internally would need to develop processes and policies to support implementation. In this case, we estimate 10 hr at $53.32/hr for a business operations specialist to develop policy and 100 hr at $73.60/hr for a computer programmer to develop, test, and automate the validation processes. In aggregate, we estimate a one-time state burden of 770 hr (7 states × 110 hr) and $55,252.40 [7 states × ((10 hr × $53.32/hr) + (100 hr × $73.60/hr))].

For a state electing to procure a vendor, given the wide variance in state procurement processes, our burden is conservatively estimated at 150 hr for writing a proposal request, evaluating proposals, and implementing the selected proposal. We estimate 125 hr at $53.32/hr for a business operations specialist to participate in the writing, evaluating, and implementing, and 25 hr at $127.72/hr for a general and operations manager to participate in the writing, evaluating, and implementing. In aggregate, we estimate an annual state burden of 1,050 hr [7 states × (150 hr)]

and $69,006.00 [7 states × ((125 hr × $53.32/hr) + (25 hr × $127.72/hr))].

Section 438.602(g) through § 457.1285, would require states to post the MCO's, PIHP's, and PAHP's contracts, data from § 438.604, and audits from § 438.602(e) on their Web site. As most of these activities will only occur no more frequently than annually, we estimate an annual state burden of 1 hr at $73.60/hr for a computer programmer to post the documents. In aggregate, we estimate 33 hr (33 states × 1 hr) and $2,428.80 (33 hr × $73.60/hr).

Section 438.608(a) through § 457.1285, would require that MCOs, PIHPs, and PAHPs have administrative and management arrangements or procedures that are designed to guard against fraud and abuse. The arrangements or procedures must include a compliance program as set forth under § 438.608(a)(1), provisions for reporting under § 438.608(a)(2), provisions for notification under § 438.608(a)(3), provisions for verification methods under § 438.608(a)(4), and provisions for written policies under § 438.608(a)(5).

The compliance program must include: Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable federal and state standards and requirements under the contract; the designation of a Compliance Officer; the establishment of a Regulatory Compliance Committee on the Board of Directors; effective training and education for the organization's management and its employees; and provisions for internal monitoring and a prompt and effective response to noncompliance with the requirements under the contract.

We estimate that reviewing their policies and procedures to ensure that all of the above listed items are addressed. We estimate this would require 5 hr at $53.32/hr for a business operations specialist to review and (if necessary) revise their policies and procedures. In aggregate, we estimate a one-time private sector burden of 315 hr (63 MCOs, PIHPs, and PAHPs × 5 hr) and $16,795.80 (315 hr × $53.32/hr).

Section 438.608(a)(2) and (3) through § 457.1285, require reporting of improper payments and enrollee fraud. As these would be done via an email from the MCO, PIHP, or PAHP to the state and do not occur very often, we estimate only 2 hr per year by a business operations specialist at $53.32/hr. We estimate an annual burden of 126 hr (63 MCOs, PIHPs, and PAHPs × 2 hr) and $6,718.32 (126 hr × $53.32/hr).

Section 438.608(a)(4) through § 457.1285, would require the MCO, PIHP, or PAHP to use a sampling methodology to verify receipt of services. This typically involves mailing a letter or sending an email to the enrollee, we estimate 33 states mail to 100 enrollees each (33 × 100 = 3,300 mailings) taking 1 min at $29.92/hr for a mail clerk. We estimate a total annual aggregate burden for private sector of 55 hr (3,300 mailings × 1 min) and $1,645.60 (55 hr × $9.92/hr). This estimate will be significantly reduced as the use of email increases.

Section 438.608(c) and (d) through § 457.1285, would require states to include in all MCO, PIHP, and PAHP contracts, the process for the disclosure and treatment of certain types of recoveries and reporting of such activity. The burden to amend the contracts is included in § 457.1201. We estimate the burden to comply with the reporting to include 1 hr at $73.60/hr for a computer programmer to create the report. In aggregate, we estimate a one-time private sector burden of 63 hr (63 MCOs, PIHPs, and PAHPs × 1 hr) and $4,636.80 (63 hr × $73.60/hr). Once developed, the report would be put on a production schedule and add no additional burden.

D. Summary of Proposed Burden Estimates

Table 2 sets out our proposed annual burden estimates. While the annual burden estimates (under Frequency) are unchanged, the one-time estimates have been annualized by dividing the one-time hour and cost figures by 3 to account for OMB's 3-year approval period.

The burden associated with this proposed rule is divided amongst four Paperwork Reduction Act (PRA) packages. The burden proposed for part 431 subpart I will be contained in a new PRA package (CMS–10553). CMS–10108 will continue to contain all of part 438, except for those provisions related to external quality review (§§ 438.350, 438.352, 438.354, 438.356, 438.358, 438.360, 438.362, 438.364, and 438.370), which will remain in the separate CMS–R–305. The proposed CHIP managed care regulation burden will be in a new PRA package, CMS–10554.

BILLING CODE 4120–01–P

TABLE 2: Summary of Proposed PRA-related Requirements and Burden

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
42 CFR 431											
431.502(a) Initial CQS	0938-New (CMS-10553)	19	19	70	1,330	53.32	3,732.40	70,915.60	once	443	23,638.53
431.502(a) Initial CQS		19	19	2	38	29.92	59.84	1,136.96	once	13	378.99
431.502(a) Initial CQS		19	19	15	285	53.32	799.80	15,196.20	once	95	5,065.40
431.502(a) Initial CQS		19	19	1	19	29.92	29.92	568.48	once	6	189.49
431.504(b) Revise CQS		18	18	25	150	53.32	1,333.00	7,998.00	annual	150	7,998.00
431.504(b) Revise CQS		18	18	2	12	29.92	59.84	359.04	annual	12	359.04
431.504(b) Revise CQS		18	18	5	30	53.32	266.60	1,599.60	annual	30	1,599.60
431.504(b) Revise CQS		18	18	1	6	29.92	29.92	179.52	annual	6	179.52
431.504(b) Update Policies		19	19	0.5	10	53.32	26.66	506.54	once	3	168.85
431.504(b) Revise CQS		19	19	25	158	53.32	1,333.00	8,442.33	annual	158	8,442.33
431.504(b) Revise CQS		19	19	2	13	29.92	59.84	378.99	annual	13	378.99
431.504(b) Revise CQS		19	19	5	32	53.32	266.60	1,688.47	annual	32	1,688.47
431.504(b) Revise CQS		19	19	1	6	29.92	29.92	189.49	annual	6	189.49
431.504(b) Revise QS to CQS		27	27	10	270	53.32	533.20	14,396.40	once	90	4,798.80
431.504(b)(1) Evaluate CQS		19	19	40	253	53.32	2,132.80	13,505.96	annual	253	13,505.96
431.504(c) Revise Policies		19	19	0.5	10	53.32	26.66	506.54	once	3	168.85
42 CFR 438											
438.3 Contracts	0938-0920 (CMS-	42	602	6	3,612	53.32	319.92	192,591.84	once	1204	64,197.28
438.5		39	50	10	500	92.00	920.00	46,000.00	annual	500	46,000.00

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
Rate Standards	10108)										
438.5Rate Standards		39	50	1	50	127.72	127.72	6,386.00	annual	50	6,386.00
438.7 Rate Certifications		39	70	1.50	105	92.00	138.00	9,660.00	annual	105	9,660.00
438.7 Rate Certifications		39	70	0.13	9	127.72	16.60	1,162.25	annual	9	1,162.25
438.7 Rate Certifications		39	70	0.73	51	73.60	53.73	3,760.96	annual	51	3,760.96
438.7 Rate Certifications		39	70	0.73	51	53.32	38.92	2,724.65	annual	51	2,724.65
438.7 Rate Certifications		39	70	0.26	18	29.92	7.78	544.54	annual	18	544.54
438.8(c) MLR		568	568	101	57,368	73.60	7,433.60	4,222,284.80	once	19123	1,407,428.27
438.8(c) MLR		568	568	50	28,400	53.32	2,666.00	1,514,288.00	once	9467	504,762.67
438.8(c) MLR		568	568	17	9,656	127.72	2,171.24	1,233,264.32	once	3219	411,088.11
438.8(c) MLR		568	568	32	18,176	73.60	2,355.20	1,337,753.60	annual	18176	1,337,753.60
438.8(c) MLR		568	568	16	9,088	53.32	853.12	484,572.16	annual	9088	484,572.16
438.8(c) MLR		568	568	5	2,840	127.72	638.60	362,724.80	annual	2840	362,724.80
438.10(c)(3) Information Requirements		42	42	6	252	73.60	441.60	18,547.20	once	84	6,182.40
438.10(c)(3) Information Requirements		42	42	3	126	73.60	220.80	9,273.60	annual	126	9,273.60
438.10(c)(4)(i) Information Requirements		42	42	6	252	53.32	319.92	13,436.64	once	84	4,478.88

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
438.10(c)(4)(ii) Information Requirements		20	20	20	400	53.32	1,066.40	21,328.00	once	133	7,109.33
438.10(c)(4)(ii)Information Requirements		20	20	2	40	53.32	106.64	2,132.80	annual	40	2,132.80
438.10(d)(2)(i) Information Requirements		42	42	6	252	53.32	319.92	13,436.64	once	84	4,478.88
438.10(e)(1) Information Requirements		42	42	1	42	53.32	53.32	2,239.44	once	14	746.48
438.10(e)(1) Information Requirements		42	2,069,259	0.0167	-30,512	26.40	0.44	-805,516.80	annual	-30512	-805,516.80
438.10(g) Information Requirements		100	100	4	400	53.32	213.28	21,328.00	once	133	7,109.33
438.10(g) Information Requirements		100	10,659,819	0.0167	177,699	26.40	0.44	4,691,258.42	once	59233	1,563,752.81
438.10(g) Information Requirements		100	2,069,259	0.0167	1,988	26.40	0.44	52,483.20	annual	1988	52,483.20
438.10(g) Information Requirements		577	577	1	577	53.32	53.32	30,765.64	annual	577	30,765.64
438.10(h) Information Requirements		577	577	1	577	73.60	73.60	42,467.20	once	192	14,155.73
438.14(c) Contracts		463	463	1	463	73.60	73.60	34,076.80	once	154	11,358.93
438.14(c) Contracts		25	25	12	300	53.32	639.84	15,996.00	annual	300	15,996.00
438.54(c)(2) Enrollment		15	15	2	30	73.60	147.20	2,208.00	once	10	736.00
438.54(c)(8) Enrollment		42	559,865	0.0167	9,350	26.40	0.44	246,833.28	annual	9350	246,833.28
438.62(b)(1) Transition of		42	42	5	210	53.32	266.60	11,197.20	once	70	3,732.40

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
Care											
438.62(b)(1) Transition of Care		568	568	1	568	53.32	53.32	30,285.76	once	189	10,095.25
438.62(b)(2) Transition of Care		568	568	4	2,272	73.60	294.40	167,219.20	once	757	55,739.73
438.62(b)(2)Transition of Care		42	42	4	168	73.60	294.40	12,364.80	once	56	4,121.60
438.62(b)(2) Transition of Care		568	313,704	0	52,294	65.40	10.90	3,420,057.47	annual	52294	3,420,057.47
438.66(a)-(b) State Monitoring		42	42	8	336	53.32	426.56	17,915.52	once	112	5,971.84
438.66(c) State Monitoring		42	42	20	840	53.32	1,066.40	44,788.80	once	280	14,929.60
438.66(d)(3) State Monitoring		20	20	5	100	127.72	638.60	12,772.00	annual	100	12,772.00
438.66(d)(3) State Monitoring		20	20	30	600	53.32	1,599.60	31,992.00	annual	600	31,992.00
438.66(d)(3) State Monitoring		20	20	5	100	73.60	368.00	7,360.00	annual	100	7,360.00
438.66(d)(3) State Monitoring		20	20	5	100	127.72	638.60	12,772.00	annual	100	12,772.00
438.66(d)(3) State Monitoring		20	20	30	600	53.32	1,599.60	31,992.00	annual	600	31,992.00
438.66(d)(3) State Monitoring		20	20	5	100	73.60	368.00	7,360.00	annual	100	7,360.00
438.66(e)(1-2) State Monitoring		42	42	6	252	53.32	319.92	13,436.64	annual	252	13,436.64

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
438.68(a)-(c) Network Adequacy		20	20	10	200	53.32	533.20	10,664.00	once	67	3,554.67
438.68(a)-(c) Network Adequacy		16	16	10	160	53.32	533.20	8,531.20	once	53	2,843.73
438.68(d) Network Adequacy		40	40	3	120	53.32	159.96	6,398.40	once	40	2,132.80
438.70(c) MLTSS Engagement		14	14	4	56	53.32	213.28	2,985.92	annual	56	2,985.92
438.71(a) Beneficiary Support System		20	20	125	2,500	53.32	6,665.00	133,300.00	once	833	44,433.33
438.71(a) Beneficiary Support System		20	20	25	500	127.72	3,193.00	63,860.00	once	167	21,286.67
438.71(b)Beneficiary Support System		42	42	3	126	53.32	159.96	6,718.32	once	42	2,239.44
438.71(b) Beneficiary Support System		42	42	1	42	53.32	53.32	2,239.44	annual	42	2,239.44
438.110(a) Member Advisory Committee		14	14	6	84	53.32	319.92	4,478.88	annual	84	4,478.88
438.207(b)-(d) Adequate Capacity		568	568	1	568	73.60	53.32	30,285.76	once	189	10,095.25
438.207(b)-(d) Adequate Capacity		568	568	2	1,136	53.32	106.64	60,571.52	annual	1136	60,571.52
438.208(b)(2)(iii)		568	2,746,476	0.1667	457,746	59.20	9.87	27,099,105.17	annual	457746	27,099,105.17

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
Care Coordination											
438.208(b)(3) Care Coordination		168	168	3	504	53.32	159.96	26,873.28	once	168	8,957.76
438.208(b)(3) Care Coordination		168	485,872	0.1667	80,980	29.68	4.95	2,403,494.90	annual	80980	2,403,494.90
438.208(b)(4) Care Coordination		568	568	4	-462,510	73.60	294.40	-34,040,736.00	once	80980	-11,346,912.00
438.208(c)(2)-(3) Care Coordination		568	428,128	1	428,128	65.40	65.40	27,999,571.20	annual	428128	27,999,571.20
438.208(c)(3)(v) Care Coordination		568	568	1	568	53.32	53.32	30,285.76	once	189	10,095.25
438.210(a)(4)(ii)(B) Authorization of Services		568	568	20	11,360	65.40	1,308.00	742,944.00	once	3787	247,648.00
438.210(c) Authorization of Services		61	61	1.0	61	53.32	53.32	3,252.52	once	20	1,084.17
438.230 Subcontracts		568	568	3.0	1,704	53.32	159.96	90,857.28	once	568	30,285.76
438.242(b)(2) Health Information		41	41	20	820	73.60	1,472.00	60,352.00	once	273	20,117.33
438.310(c)(2) State PCCM Assessment		10	10	2	20	53.32	106.64	1,066.40	once	7	355.47
438.330(a)(2) State QAPI Programming		40	40	10	133	73.60	736.00	9,810.88	annual	133	9,810.88
438.330(a)(2)(ii) State QAPI Exemption		11	11	1	4	53.32	53.32	197.28	annual	4	197.28

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
438.330(b)(3) Create PCCM Utilization Review Policies		15	15	10	150	53.32	533.20	7,998.00	once	50	2,666.00
438.330(b)(3) Operate PCCM Utilization Review Policies		15	15	10	150	53.32	533.20	7,998.00	annual	150	7,998.00
438.330(c)(1)-(3) MCO/PIHP Performance Measures		511	1,533	0.1	153	53.32	5.33	8,173.96	annual	153	8,173.96
438.330(c)(1)-(3) PAHP/PCCM Performance Measures		56	168	4	672	53.32	213.28	35,831.04	annual	672	35,831.04
438.330(c)(4) MLTSS Performance Measures		179	358	4	1,432	53.32	213.28	76,354.24	annual	1432	76,354.24
438.330(d)(1)-(2) MCO/PIHP PIPs		511	1,533	8	12,264	53.32	426.56	653,916.48	annual	12264	653,916.48
438.330(d)(1)-(2) Create PAHP PIP Policies		41	41	2	82	53.32	106.64	4,372.24	once	27	1,457.41
438.330(d)(1)-(2) PAHP PIPs		41	41	8	328	53.32	426.56	17,488.96	annual	328	17,488.96
438.330(e) Assess PCCMs		15	15	15	225	53.32	799.80	11,997.00	annual	225	11,997.00
438.330(e)(1)(ii) Update State		40	40	0.5	20	53.32	26.66	1,066.40	once	7	355.47

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
Policies											
438.330(e)(1)(ii) State Review of Outcomes		40	40	1	40	53.32	53.32	2,132.80	annual	40	2,132.80
438.330(c)(1)(iii) Update State Policies		16	16	0.5	8	53.32	26.66	426.56	once	3	142.19
438.330(e)(1)(iii) State Assess LTSS		16	16	1	16	53.32	53.32	853.12	annual	16	853.12
438.332(a) State Purchase Accreditation Standards		20	20	N/A	N/A	N/A	20,000.00	133,333.33	annual	N/A	133,333.33
438.332(a) Develop State Standards		20	20	15	100	53.32	799.80	5,332.00	annual	100	5,332.00
438.332(a) Develop State Standards		20	20	5	33	127.72	638.60	4,257.33	annual	33	4,257.33
438.332(a) State Review of Plans		20	276	80	7,360	53.32	4,265.60	392,435.20	annual	7360	392,435.20
438.332(a) State Review of Plans		20	276	5	460	127.72	638.60	58,751.20	annual	460	58,751.20
438.332(a) State Review of Plans		20	276	5	460	29.92	149.60	13,763.20	annual	460	13,763.20
438.332(a) Provide Plan Information		276	276	40	3,680	53.32	2,132.80	196,217.60	annual	3680	196,217.60
438.332(a) Provide Plan Information		276	276	5	460	29.92	149.60	13,763.20	annual	460	13,763.20
438.332(a) Provide Plan Information		276	276	4	368	127.72	510.88	47,000.96	annual	368	47,000.96

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
438.332(b) State Review Deeming Process		20	20	40	267	53.32	2,132.80	14,220.44	annual	267	14,220.44
438.332(b)(2) Initial Plan Accreditation		138	138	N/A	N/A	N/A	70,700.00	9,756,600.00	once	N/A	3,252,200.00
332(b)(2) Plan Accreditation Renewal		138	138	N/A	N/A	N/A	70,700.00	3,252,200.00	annual	N/A	3,252,200.00
438.334(a) Create State QRS		30	30	100	3,000	53.32	5,332.00	159,960.00	once	1000	53,320.00
438.334(a) Create State QRS		30	30	40	1,200	73.60	2,944.00	88,320.00	once	400	29,440.00
438.334(a) Create State QRS		30	30	15	450	127.72	1,915.80	57,474.00	once	150	19,158.00
438.334(a) Create State QRS		30	30	2	60	29.92	59.84	1,795.20	once	20	598.40
438.334(a) Create State QRS		30	30	15	450	53.32	799.80	23,994.00	once	150	7,998.00
438.334(b) State Rates Plans		30	414	20	8,280	53.32	1,066.40	441,489.60	annual	8280	441,489.60
438.334(c) State QRS Exemption		10	10	5	50	53.32	266.60	2,666.00	once	17	888.67
438.334(d) Use MA Rating		25	-25	20	-500	53.32	1,066.40	-26,660.00	annual	-500	-26,660.00
438.340 CQS Managed Care Elements		40	40	10	133	53.32	533.20	7,107.56	annual	133	7,107.56
438.340 Removal of		15	-15	80	-1,200	N/A	N/A	N/A	once	-400	

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
438.204(b)(2)											
438.358(b)(1)-(3) MCO/PIHP Mandatory EQR-Related Activities		40	511	474.3	242,367	53.32	25,289.68	12,923,024.44	annual	242367	12,923,024.44
438.358(b)(1)-(3) PAHP Mandatory EQR-Related Activities		40	41	344.3	14,116	53.32	18,358.08	752,681.12	annual	14116	752,681.12
438.358(b)(1)-(4) Plan Information for Mandatory EQR-Related Activities		552	552	100	18,560	53.32	5,332.00	634,944.00	annual	18560	634,944.00
438.358(b)(1)-(4) Plan Information for Mandatory EQR-Related Activities		552	552	100	18,560	29.92	2,992.00	1,211,904.00	annual	18560	1,211,904.00
438.358(b)(4) MCO/PIHP/PAHP Mandatory EQR-Related Activity		40	552	60	33,120	53.32	3,199.20	1,765,958.40	annual	33120	1,765,958.40
438.358(c) MCO/PIIP Optional EQR-Related Activities		40	51	70	3,570	127.72	8,940.40	455,960.40	annual	3570	455,960.40

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
438.358(c) MCO/PIHP Optional EQR-Related Activities		40	51	87.5	4,463	73.60	6,440.00	328,440.00	annual	4463	328,440.00
438.358(c) MCO/PIHP Optional EQR-Related Activities		40	51	192.5	9,818	53.32	10,264.10	523,469.10	annual	9818	523,469.10
438.358(c) MCO/PIHP Optional EQR-Related Activities		40	25	30	750	127.72	3,831.60	95,790.00	annual	750	95,790.00
438.358(c) MCO/PIHP Optional EQR-Related Activities		40	25	37.5	938	73.60	2,760.00	69,000.00	annual	938	69,000.00
438.358(c) MCO/PIHP Optional EQR-Related Activities		40	25	82.5	2,063	53.32	4,398.90	109,972.50	annual	2063	109,972.50
438.358(c) MCO/PIHP Optional EQR-Related Activities		40	26	10	260	127.72	1,277.20	33,207.20	annual	260	33,207.20
438.358(c) MCO/PIHP Optional EQR-Related Activities		40	26	12.5	325	73.60	920.00	23,920.00	annual	325	23,920.00
438.358(c) MCO/PIHP Optional EQR-Related Activities		40	26	27.5	715	53.32	1,466.30	38,123.80	annual	715	38,123.80
438.358(c) MCO/PIHP		40	51	31.8	1,622	127.72	4,061.50	207,136.30	annual	1622	207,136.30

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
Optional EQR-Related Activities											
438.358(c) MCO/PIHP Optional EQR-Related Activities		40	51	39.75	2,027	73.60	2,925.60	149,205.60	annual	2027	149,205.60
438.358(c) MCO/PIHP Optional EQR-Related Activities		40	51	87.45	4,460	53.32	4,662.83	237,804.53	annual	4460	237,804.53
438.358(c) MCO/PIHP Optional EQR-Related Activities		40	51	39	1,989	127.72	4,981.08	254,035.08	annual	1989	254,035.08
438.358(c) MCO/PIHP Optional EQR-Related Activities		40	51	48.75	2,486	73.60	3,588.00	182,988.00	annual	2486	182,988.00
438.358(c) MCO/PIHP Optional EQR-Related Activities		40	51	107.25	5,470	53.32	5,718.57	291,647.07	annual	5470	291,647.07
438.358(c) MCO/PIHP Optional EQR-Related Activities		40	51	39	1,989	127.72	4,981.08	254,035.08	annual	1989	254,035.08
438.358(c) MCO/PIHP Optional EQR-Related Activities		40	51	48.75	2,486	73.60	3,588.00	182,988.00	annual	2486	182,988.00
438.358(c) MCO/PIHP Optional EQR-Related		40	51	107.25	5,470	53.32	5,718.57	291,647.07	annual	5470	291,647.07

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
Activities											
438.358(c) PAHP Optional EQR-Related Activities		4	4	70	280	127.72	8,940.40	35,761.60	annual	280	35,761.60
438.358(c) PAHP Optional EQR-Related Activities		4	4	87.5	350	73.60	6,440.00	25,760.00	annual	350	25,760.00
438.358(c) PAHP Optional EQR-Related Activities		4	4	192.5	770	53.32	10,264.10	41,056.40	annual	770	41,056.40
438.358(c) PAHP Optional EQR-Related Activities		4	4	15	60	127.72	1,915.80	7,663.20	annual	60	7,663.20
438.358(c) PAHP Optional EQR-Related Activities		4	4	18.75	75	73.60	1,380.00	5,520.00	annual	75	5,520.00
438.358(c) PAIP Optional EQR-Related Activities		4	4	41.25	165	53.32	2,199.45	8,797.80	annual	165	8,797.80
438.358(c) PAHP Optional EQR-Related Activities		4	4	5	20	127.72	638.60	2,554.40	annual	20	2,554.40
438.358(c) PAHP Optional EQR-Related Activities		4	4	6.25	25	73.60	460.00	1,840.00	annual	25	1,840.00

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
438.358(c) PAHP Optional EQR-Related Activities		4	4	13.75	55	53.32	733.15	2,932.60	annual	55	2,932.60
438.358(c) PAHP Optional EQR-Related Activities		4	4	31.8	127	127.72	4,061.50	16,245.98	annual	127	16,245.98
438.358(c) PAHP Optional EQR-Related Activities		4	4	39.75	159	73.60	2,925.60	11,702.40	annual	159	11,702.40
438.358(c) PAHP Optional EQR-Related Activities		4	4	87.45	350	53.32	4,662.83	18,651.34	annual	350	18,651.34
438.358(c) PAHP Optional EQR-Related Activities		4	4	39	156	127.72	4,981.08	19,924.32	annual	156	19,924.32
438.358(c) PAHP Optional EQR-Related Activities		4	4	48.75	195	73.60	3,588.00	14,352.00	annual	195	14,352.00
438.358(c) PAHP Optional EQR-Related Activities		4	4	107.25	429	53.32	5,718.57	22,874.28	annual	429	22,874.28
438.358(c) PAHP Optional EQR-Related Activities		4	4	39	156	127.72	4,981.08	19,924.32	annual	156	19,924.32
438.358(c) PAHP		4	4	48.75	195	73.60	3,588.00	14,352.00	annual	195	14,352.00

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
Optional EQR-Related Activities											
438.358(c) PAHP Optional EQR-Related Activities		4	4	107.25	429	53.32	5,718.57	22,874.28	annual	429	22,874.28
438.360(b) MCO/PIHP Nonduplication Disclosure		51	51	2	102	53.32	106.64	5,438.64	annual	102	5,438.64
438.360(b) MCO/PIHP Nonduplication Disclosure		51	51	6	306	29.92	179.52	9,155.52	annual	306	9,155.52
438.360(b) PAHP Nonduplication Disclosure		4	4	2	8	53.32	106.64	426.56	annual	8	426.56
438.360(b) PAHP Nonduplication Disclosure		4	4	6	24	29.92	179.52	718.08	annual	24	718.08
438.360(b) Nonduplication Materials to EQRO		40	55	2	110	29.92	59.84	3,291.20	annual	110	3,291.20
438.360(b) State Nonduplication Offset - MCO/PIHP		40	-51	474.3	-24,189	53.32	25,289.68	-1,289,773.48	annual	-24189	-1,289,773.48
438.360(b) State Nonduplication Offset - PAHP		40	-4	344.3	-1,377	53.32	18,358.08	-73,432.30	annual	-1377	-73,432.30
438.360(b) MCO/PIHP/PAHP Nonduplicatio		55	-55	75	-4,125	53.32	3,999.00	-219,945.00	annual	-4125	-219,945.00

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
n Offset											
438.360(b) MCO/PIHP/PAHP Nonduplication Offset		55	-55	75	-4,125	29.92	2,244.00	-123,420.00	annual	-4125	-123,420.00
438.362 Exemption		40	17	2	-126	53.32	106.64	-4,187.12	annual	-126	-4,187.12
438.362 Exemption		40	17	6	102	29.92	179.52	3,051.84	annual	102	3,051.84
438.364(a) Amend EQRO Contract		40	40	0.5	20	53.32	26.66	1,066.40	once	7	355.47
438.364(b)(1) Amend EQRO Contract		10	10	0.5	5	53.32	26.66	266.60	once	2	88.87
438.364(b)(2) Provide EQR Reports		40	2,760	0.0833	-91,370	29.92	2.49	-1,092,318.40	annual	-91370	-1,092,318.40
438.370(c) Update State Policies		12	12	0.5	6	53.32	26.66	319.92	once	2	106.64
438.370(c) Submit EQRO Contract		12	12	0.25	3	29.92	7.48	89.76	once	1	29.92
438.400(b) Definitions		507	507	5	2,535	53.32	266.60	135,166.20	once	845	45,055.40
438.400(b) Definitions		40	40	5	200	53.32	266.60	10,664.00	once	67	3,554.67
438.402(a) Grievance System		41	41	10	410	127.22	1,272.20	52,160.20	once	137	17,386.73
438.402(a) Grievance System		41	41	75	3,075	53.32	3,999.00	163,959.00	once	1025	54,653.00
438.402(a) Grievance		41	41	15	615	73.60	1,104.00	45,264.00	once	205	15,088.00

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
System											
438.402(a) Grievance System		41	410	36	14,760	53.32	1,919.52	787,003.20	annual	14760	787,003.20
438.404(a) Notices		41	240,000	0.0167	4,008	26.40	0.44	105,811.20	annual	4008	105,811.20
438.408(b) Appeals		200	200	1	200	53.32	53.32	10,664.00	once	67	3,554.67
438.416 Reporting		568	240,000	0.0167	4,008	29.92	0.50	119,919.36	annual	4008	119,919.36
438.416 Reporting		56	56	3	168	73.60	220.80	12,364.80	once	56	4,121.60
438.416 Reporting		56	856,257	0.0167	14,271	29.92	0.50	426,986.82	annual	14271	426,986.82
438.420(c)(4) Continuation of Benefits		507	507	4	2,028	53.32	213.28	108,132.96	once	676	36,044.32
438.602(a)Program Integrity		42	42	6	252	53.32	319.92	13,436.64	once	84	4,478.88
438.602(b) Program Integrity		568	568	6	3,408	73.60	441.60	250,828.80	once	1136	83,609.60
438.602(e) Program Integrity		42	568	20	3,787	63.10	1,262.00	238,959.70	annual	3787	238,959.70
438.602(g) Program Integrity		40	40	1	40	73.60	73.60	2,944.00	annual	40	2,944.00
438.608(a)(1) Program Integrity		568	568	2	1,136	53.32	106.64	60,571.52	once	379	20,190.51
438.608(a)(2)-(3) Program Integrity		568	568	2	1,136	53.32	106.64	60,571.52	annual	1136	60,571.52
438.608(a)(4) Program Integrity		200	20,000	0.0167	334	26.40	0.44	8,817.60	annual	334	8,817.60
438.608(c)-(d) Program Integrity		568	568	1	568	73.60	73.60	41,804.80	once	189	13,934.93

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
438.722 Disenrollment Notices		12	12	1	12	53.32	53.32	639.84	annual	12	639.84
438.722 Disenrollment Notices		12	1,084,536	0.0167	18,075	26.40	0.44	477,195	annual	18075	477,195
438.818(a)(2) Encounter Data		9	9	1	9	53.32	53.32	479.88	once	3	159.96
438.818(a)(2) Encounter Data		9	9	10	90	53.32	533.20	4,798.80	once	30	1,599.60
438.818(a)(2) Encounter Data		9	9	100	900	73.60	7,360.00	66,240.00	once	300	22,080.00
438.818(a)(2) Encounter Data		9	9	125	1,125	53.32	6,665.00	59,985.00	annual	375	59,985.00
438.818(a)(2) Encounter Data		9	9	25	225	127.72	3,193.00	28,737.00	annual	75	28,737.00
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457.760(a) Quality	0938-new (CMS-10554)	33	33	3.333	110	53.32	178	5,864.61	annual	110	5,864.61
457.1201 Contracts		66	66	6	396	53.32	320	21,114.72	once	132	7,038.24
457.1206 Contracts		3	3	4	12	53.32	213	639.84	once	4	213.28
457.1207 Information Requirements		33	33	4	132	53.32	213	7,038.24	annual	132	7,038.24
457.1207 Information Requirements		33	33	6	198	73.60	442	14,572.80	once	66	4,857.60
457.1207 Information Requirements		33	33	3	99	73.60	221	7,286.40	annual	99	7,286.40
457.1207 Information Requirements		33	33	6	198	53.32	320	10,557.36	once	66	3,519.12
457.1207 Information		15	15	40	600	53.32	2,133	31,992.00	once	200	10,664.00

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
Requirements											
457.1207 Information Requirements		15	15	2	30	53.32	107	1,599.60	annual	30	1,599.60
457.1207 Information Requirements		33	33	4	132	73.60	294	9,715.20	once	44	3,238.40
457.1207 Information Requirements		33	33	6	198	53.32	320	10,557.36	once	66	3,519.12
457.1207 Information Requirements		15	15	40	600	53.32	2,133	31,992.00	once	200	10,664.00
457.1207 Information Requirements		33	306937	0	5,116	29.92	0	153,059.25	once	1705	51,019.75
457.1207 Information Requirements		33	33	1	33	53.32	53	1,759.56	once	11	586.52
457.1208 Contracts		25	25	12	300	53.32	640	15,996.00	annual	300	15,996.00
457.1210(a) Enrollment		33	306937	0.01666667	5,116	29.92	0	153,059.25	annual	5116	153,059.25
457.1214 Conflict		5	5	10	50	53.32	533	2,666.00	once	17	888.67
457.1216 Continued services		33	33	10	330	53.32	533	17,595.60	once	110	5,865.20
457.1216 Continued services		33	33	4	132	73.60	294	9,715.20	once	44	3,238.40
457.1218 Network		12	12	15	180	53.32	800	9,597.60	once	60	3,199.20
457.1218 Network		5	5	10	50	53.32	533	2,666.00	once	17	888.67
457.1218 Network		33	33	3	99	53.32	160	5,278.68	once	33	1,759.56
457.1224 Marketing		25	25	3	75	53.32	160	3,999.00	annual	75	3,999.00

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
457.1260 Grievances		33	33	5	165	53.32	267	8,797.80	annual	165	8,797.80
457.1270 Sanctions		8	8	1	8	53.32	53	426.56	annual	8	426.56
457.1270 Sanctions		30000	30000	0.02	500	26.40	0	13,200.00	annual	500	13,200.00
457.1270 Sanctions		15	15	1/2	8	53.32	27	399.90	annual	8	399.90
457.1285 Program integrity		33	33	50	1,650	53.32	2,666	87,978.00	once	550	29,326.00
457.1285 Program integrity		7	7	1	7	53.32	53	373.24	once	2	124.41
457.1285 Program integrity		7	7	10	70	53.32	533	3,732.40	once	23	1,244.13
457.1285 Program integrity		7	7	100	700	73.60	7,360	51,520.00	once	233	17,173.33
457.1285 Program integrity		7	7	125	875	53.32	6,665.00	46,655.00	annual	875	46,655.00
457.1285 Program integrity		7	7	25	175	127.72	3,193.00	22,351.00	annual	175	22,351.00
457.1285 Program integrity		33	33	1	33	73.60	73.60	2,428.80	annual	33	2,428.80
457.1205 MLR		62	62	101	6,262	73.60	7,434	460,883.20	once	2087	153,627.73
457.1205 MLR		62	62	50	3,100	53.32	2,666	165,292.00	once	1033	55,097.33
457.1205 MLR		62	62	17	1,054	127.72	2,171	134,616.88	once	351	44,872.29
457.1205 MLR		62	62	31.8	1,972	73.60	2,340	145,109.76	annual	1972	145,109.76
457.1205 MLR		62	62	15.9	986	53.32	848	52,562.86	annual	938	52,562.86
457.1205 MLR		62	62	5.3	329	127.72	677	41,968.79	annual	329	41,968.79

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
457.1207 Information Requirements		5	5	10	50	53.32	533	2,666.00	once	17	888.67
457.1207 Information Requirements		20	20	4	80	53.32	213	4,265.60	once	27	1,421.87
457.1207 Information Requirements		66	3069371	0	51,156	29.92	0	1,530,593.01	once	17052	510,197.67
457.1207 Information Requirements		66	306937	0	5,116	29.92	0	153,059.25	annual	5116	153,059.25
457.1207 Information Requirements		66	66	1	66	53.32	53	3,519.12	once	22	1,173.04
457.1207 Information Requirements		66	66	1	66	73.60	74	4,857.60	once	22	1,619.20
457.1208 Contracts		40	40	1	40	73.60	74	2,944.00	once	13	981.33
457.1216 Continued services		66	66	4	264	73.60	294	19,430.40	once	88	6,476.80
457.1216 Continued services		30000	30000	1/6	5,000	65.40	11	327,000.00	annual	5000	327,000.00
457.1222 Communication		3	3	1	3	53.32	53	159.96	annual	3	159.96
457.1222 Communication		3	3	4	12	53.32	213	639.84	annual	12	639.84
457.1222 Communication		3	234,000	0	3,900	29.92	0	116,688.00	annual	3900	116,688.00
457.1224 Marketing		5	5	2	10	53.32	107	533.20	once	3	177.73
457.1260 Grievances		62	2232	3	6,696	53.32	160	357,030.72	annual	6696	357,030.72
457.1260 Grievances		62	62	10	620	127.72	1,277	79,186.40	once	207	26,395.47
457.1260		62	62	75	4,650	53.32	3,999	247,938.00	once	1550	82,646.00

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
Grievances											
457.1260 Grievances		62	62	15	930	73.60	1,104	68,448.00	once	310	22,816.00
457.1260 Grievances		62	297,600	1/2	148,800	53.32	27	7,934,016.00	annual	148800	7,934,016.00
457.1260 Grievances		306937	306937	0	5,116	29.92	0	153,059.25	annual	5116	153,059.25
457.1260 Grievances		6139	6139	0	102	29.92	0	3,061.31	annual	102	3,061.31
457.1285 Program integrity		63	63	5	315	53.32	267	16,795.80	once	105	5,598.60
457.1285 Program integrity		63	63	2	126	53.32	107	6,718.32	annual	126	6,718.32
457.1285 Program integrity		33	3300	0	55	29.92	0	1,645.60	annual	55	1,645.60
457.1285 Program integrity		63	63	1	63	73.60	74	4,636.80	once	21	1,545.60
457.1230(a) Access Standards		63	63	3	189	53.32	160	10,077.48	once	63	3,359.16
457.1230(b) Access Standards		63	63	20	1,260	53.32	1,066	67,183.20	annual	1260	67,183.20
457.1230(b) Access Standards		63	63	1	63	53.32	53	3,359.16	annual	63	3,359.16
457.1230(c) Access Standards		122775	122775	1/6	20,463	59.20	10	1,211,380.00	annual	20463	1,211,380.00
457.1230(c) Access Standards		18	18	3	54	53.32	160	2,879.28	once	18	959.76
457.1230(c) Access Standards		613,874	613,874	1/6	102,312	29.92	5	3,061,185.01	annual	102312	3,061,185.01
457.1230(c) Access Standards		63	63	4	252	73.60	294	18,547.20	once	84	6,182.40

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
457.1230(c) Access Standards		61387	61387	1	61,387	65.40	65	4,014,709.80	annual	61387	4,014,709.80
457.1230(d) Access Standards		63	98280	0.5	49,140	65.40	33	3,213,756.00	annual	49140	3,213,756.00
457.1233(b) Structure and Operations		63	63	3	189	53.32	160	10,077.48	once	63	3,359.16
457.1233(c) Structure and Operations		62	62	2	124	53.32	107	6,611.68	annual	124	6,611.68
457.1233(d) Structure and Operations		59	59	20	1,180	73.60	1,472	86,848.00	once	393	28,949.33
457.1240(b) Quality		33	33	3.33333333	110	73.60	245	8,096.00	once	37	2,698.67
457.1240(b) Quality		2	2	0.33	1	53.32	18	35.19	annual	1	35.19
457.1240(b) Quality		3	3	10	30	53.32	533	1,599.60	annual	30	1,599.60
457.1240(b) Quality		7	21	4	84	53.32	213	4,478.88	annual	84	4,478.88
457.1240(b) Quality		4	4	2	8	53.32	107	426.56	once	3	142.19
457.1240(b) Quality		59	177	8	1,416	53.32	427	75,501.12	annual	1416	75,501.12
457.1240(b) Quality		4	4	8	32	53.32	427	1,706.24	annual	32	1,706.24
457.1240(b) Quality		3	3	15	45	53.32	800	2,399.40	annual	45	2,399.40
457.1240(b) Quality		33	33	0.5	17	53.32	27	879.78	once	6	293.26
457.1240(b) Quality		33	33	1	33	53.32	53	1,759.56	annual	33	1,759.56
457.1240(c) Quality		66	66	80	1,760	53.32	4,265.60	93,843.20	annual	1760	93,843.20
457.1240(c) Quality		66	66	5	110	127.72	638.60	14,049.20	annual	110	14,049.20
457.1240(c) Quality		66	66	5	110	29.92	149.60	3,291.20	annual	110	3,291.20

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
457.1240 Quality		66	66	40	880	53.32	2,132.80	46,921.60	annual	880	46,921.60
457.1240 Quality		66	66	5	110	29.92	149.60	3,291.20	annual	110	3,291.20
457.1240 Quality		66	66	4	88	127.72	510.88	11,239.36	annual	88	11,239.36
457.1240 Quality		66	66	30	1,980	53.32	1,600	105,573.60	annual	1980	105,573.60
457.1240 Quality		66	66	5	330	127.72	639	42,147.60	annual	330	42,147.60
457.1240 Quality		66	66	5	330	29.92	150	9,873.60	annual	330	9,873.60
457.1240(c) Quality		16	16	N/A	N/A	N/A	70,700.00	1,131,200.00	once		377,066.67
457.1240(c) Quality		16	16	N/A	N/A	N/A	70,700.00	377,066.67	annual		377,066.67
457.1240(d) Quality		47	47	20	940	53.32	1,066.40	50,120.80	annual	940	50,120.80
457.1240(d) Quality		33	33	3.33333333	110	53.32	177.73	5,865.20	once	37	1,955.07
457.1250(a) EQR		5	5	125	625	53.32	6,665	33,325.00	once	208	11,108.33
457.1250(a) EQR		5	5	50	250	73.60	3,680	18,400.00	once	83	6,133.33
457.1250(a) EQR		5	5	10	50	127.72	1,277	6,386.00	once	17	2,128.67
457.1250(a) EQR		5	5	2	10	53.32	107	533.20	once	3	177.73
457.1250(a) EQR		5	15	65	975	53.32	3,466	51,987.00	annual	975	51,987.00
457.1250(a) EQR		5	15	53	795	53.32	2,826	42,389.40	annual	795	42,389.40
457.1250(a) EQR		5	5	120.333333	602	53.32	6,416	32,080.87	annual	602	32,080.87
457.1250(a) EQR		5	5	60	300	53.32	3,199	15,996.00	annual	300	15,996.00
457.1250(a) EQR		5	5	80	400	53.32	4,266	21,328.00	annual	400	21,328.00
457.1250(a) EQR		5	5	80	400	29.92	2,394	11,968.00	annual	400	11,968.00
457.1250(a)		48	48	350	16,800	53.32	18,662	895,776.00	annual	16800	895,776.00

CFR Section	OMB control Number	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Frequency	Annualized hours*	Annualized costs ($)
EQR											
457.1250(a) EQR		30	30	50	1,500	53.32	2,666	79,980.00	annual	1500	79,980.00
457.1250(a) EQR		20	20	159	3,180	53.32	8,478	169,557.60	annual	3180	169,557.60
457.1250(a) EQR		26	26	195	5,070	53.32	10,397	270,332.40	annual	5070	270,332.40
457.1250(a) EQR		52	52	159	8,268	53.32	8,478	440,849.76	annual	8268	440,849.76
457.1250(a) EQR		52	310	0	26	29.92	2	772.93	annual	26	772.93
TOTAL					1,803,056	--		108,439,506.50	---	--	111,623,115.30

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E. Exempt ICRs

1. Administrative Actions

While the requirements under §§ 431.220(a)(5) and (6), 431.220(b), 438.710(b)(2), 438.730(b), and 457.1270(a), (b), and (c) are subject to the PRA, since the information collection requirements are associated with an administrative action (5 CFR 1320.4(a)(2) and (c)), they are exempt from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

Section 431.220(a)(5) and (6) would add PAHP enrollees as eligible for a state fair hearing as permitted in subpart B of 42 CFR part 438. Section 431.220(b) prescribes procedures for an opportunity for a hearing if the state agency or non-emergency transportation PAHP takes action to suspend, terminate, or reduce services, or an MCO, PIHP or PAHP takes action under subpart.

Before imposing any of the sanctions specified in subpart I, § 438.710(a) would require that the state give the affected MCO, PIHP, PAHP or PCCM written notice that explains the basis and nature of the sanction. Section 438.710(b)(2) states that before terminating an MCO's, PIHP's, PAHP's or PCCM's contract, the state would be required to: (1) Give the MCO or PCCM written notice of its intent to terminate, the reason for termination, the time and place of the hearing; (2) give the entity written notice (after the hearing) of the decision affirming or reversing the proposed termination of the contract and, for an affirming decision, the effective date of termination; and (3) give enrollees of the MCO or PCCM notice (for an affirming decision) of the termination and information, consistent with § 438.10, on their options for receiving Medicaid services following the effective date of termination.

Section 438.730(b) would require that if CMS accepts a state agency's recommendation for a sanction, the state agency would be required to give the MCO written notice of the proposed sanction. Section 438.730(c) would require that if the MCO submits a timely response to the notice of sanction, the state agency must give the MCO a concise written decision setting forth the factual and legal basis for the decision. If CMS reverses the state's decision, the state must send a copy to the MCO.

Section 457.1270 would apply subpart I (Sanctions) of part 438 to CHIP. Within subpart I, § 438.710(a) would require that the state provide the affected entity with timely written notice of the basis of the sanction. Section 438.710(b) would require that the state provide an entity a pre-termination hearing. If we accept a state agency's recommendation for a sanction, § 438.730(b) would require that the agency provide the MCO, PIHP or PAHP written notice of the proposed sanction. If the MCO submits a timely response to the notice of sanction, § 438.730(c) would require that the state agency provide the MCO, PIHP or PAHP with a concise written decision setting forth the factual and legal basis for the decision. If we reverse the state's decision, the state must send a copy to the affected MCO, PIHP or PAHP.

2. Fewer Than 10 Respondents

While the requirements under §§ 438.8(m), 438.70(a), 438.102(a)(2), 438.350(a)(1) and (2), 438.360(c), 438.724, and 438.818(d) are subject to the PRA, in each instance we estimate fewer than 10 respondents. Consequently, the information collection requirements are exempt (5 CFR 1320.3(c)) from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Section 438.8(m) would require the MCO, PIHP, or PAHP to recalculate its MLR for any year in which a retroactive capitation change is made. As such retroactive adjustments are not a common practice, we only estimate that no more than three plans per year may have to recalculate their MLR.

Section 438.70(a) would require that states have a process to solicit and address viewpoints from beneficiaries, providers, and other stakeholders as part of the design, implementation, and oversight of the managed LTSS program. We estimate no more than 3 states per year would elect to move to a managed LTSS program.

Section 438.102(a)(2) specifies that MCOs, PIHPs, and PAHPs are not required to cover, furnish, or pay for a particular counseling or referral service if the MCO, PIHP, or PAHP objects to the provision of that service on moral or religious grounds; and that written information on these policies is made available to: Prospective enrollees, before and during enrollment; and current enrollees, within 90 days after adopting the policy for an any particular service. We believe the burden associated with this requirement affects no more than 3 MCOs or PIHPs annually since it applies only to the services they discontinue providing on moral or religious grounds during the contract period. PAHPs are excluded from this estimate because they generally do not provide services that would be affected by this provision.

Section § 438.350 would add PAHPs to the list of affected entities in § 438.350(a)(1) and (2). The addition of PAHPs to the EQR process would require the nine states with PAHPs and existing EQRO contracts to modify their existing EQRO contracts. The estimated 3 states with PAHPs that do not currently have an EQRO contract would need to enter into a contract with an EQRO.

Section 438.360(c) would require states to document, in the comprehensive quality strategy required at § 431.502, which mandatory EQR-related activities it will apply the non-duplication provisions to, and why it believes these activities would be duplicative. Given that this is already standard practice for the 37 states that currently contract with MCOs and/or PIHPs, only the 3 states that contract only with PAHPs would have to revise their policies and procedures to include this in their comprehensive quality strategy.

Section 438.724 would require that the state provide written notice to their CMS Regional Office whenever it imposes or lifts a sanction on a PCCM or PCCM entity. Given the limited scope of benefits provided by a PCCM or PCCM entity, we anticipate that no more than 3 states may impose or lift a sanction on a PCCM or PCCM entity in any year.

Section 438.818(d) would require states new to managed care and not previously submitting encounter data to MSIS to submit an Implementation plan. There are currently only 8 states that do not use MCOs thus these would be the only states that may have to submit an Implementation plan should they adopt managed care in the future.

3. Usual and Customary Business Practices

Section 433.138(e)(1) would make a technical correction addressing state Medicaid agencies' review of claims with trauma codes, to identify instances where third party liability (TPL) may exist for expenditures for medical assistance covered under the state plan. The correction would remove references to the International Classification of Disease, 9th edition, Clinical Modification Volume 1 (ICD–9–CM) by replacing the references with a general description of the types of medical diagnoses indicative of trauma. States would use the International Classification of Disease that they are using at the time of claims processing. There is no additional cost to the state related to the proposed changes to § 433.138(e) because the proposed changes do not require any action by the

state, if the state wishes to retain their usual and customary editing for the same types of traumatic injuries currently identified with ICD–9–CM.

While the requirements under §§ 438.10(c)(7), 438.208(b)(2), 438.208(b)(2)(i) and (iv), 438.208(b)(5), 438.210(b), 438.214, 438.360(c), 438.406(b)(5), 438.408(b)(2) and (3), 438.408(f)(1) and (2), and 438.416(b) and (c) are subject to the PRA, we believe the associated burden is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with the aforementioned requirements would be incurred by persons during the normal course of their activities and, therefore, should be considered usual and customary business practices.

Section 438.10(c)(7) would add PAHPs and PCCMs to the managed care entities that must have mechanisms in place to help enrollees and potential enrollees understand the requirements and benefits of managed care.

Section 438.208(b)(2) would require that MCOs, PIHPs and PAHPs coordinate an enrollee's care between settings or with services received through a different MCO, PIHP, PAHP and FFS. Section 438.208(b)(2)(i) would require discharge planning which has been a long standing industry practice since managed care plans consistently require authorization for all inpatient and facility care.

Section 438.208(b)(5) would require providers to maintain a record according to medical industry accepted professional standards.

Section 438.210(b) would require contracts with MCOs, PIHPs, or PAHPs and its subcontractors to have written policies and procedures for the processing of requests for initial and continuing authorizations of services. The burden associated with this requirement is the time required to develop the policies and procedures which is standard industry practice for managed care plans.

In § 438.214, each state must ensure, through its contracts, that each MCO, PIHP, or PAHP implements written policies and procedures for the selection and retention of providers. Since all managed care programs utilize provider networks, this is industry standard practice.

Section 438.360(c) would require states to document, in the comprehensive quality strategy required at § 431.502, which mandatory EQR-related activities it will apply the non-duplication provisions to, and why it believes these activities would be duplicative. Given that this is already standard practice for the 37 states that currently contract with MCOs and/or PIHPs, only the three states that contract only with PAHPs would have to revise their policies and procedures to include this in their comprehensive quality strategy.

Section 438.406(b)(5) would modify the language for evidence standards for appeals to mirror the private market evidence standards. This aligns the text with commercial requirements but does not alter the meaning.

Section 438.408(b)(2) would change the timeframe an entity has to reach a determination from 45 days to 30 days to align with Medicare. Most insurers offer more than one line of business, and therefore we believe this timeframe will allow MCOs, PIHPs, and PAHPs to be consistent with their usual and customary business practices and reduce their burden. Section 438.408(b)(3) would change the timeframe an entity has to reach a determination in an expedited appeal from 3 days to 72 hr to align with Medicare and the private market. Most insurers offer more than one line of business, and therefore we believe this timeframe will make Medicaid consistent with usual and customary business practices and reduce their burden. Section 438.408(f)(1) and (2) would require that an enrollee exhaust the appeals process before proceeding to the state fair hearing process, and change the timeframe in which a beneficiary must request a state fair hearing to 120 days. MCOs, PIHPs, and PAHPs would no longer have to maintain an appeal and a fair hearing simultaneously which will decrease administrative burdens. The changing of the timeframe to request a state fair hearing from ''not less than 20 or in excess of 90 days'' to 120 days aligns with the private market. Many insurers offer more than one line of business, and therefore we believe aligning these timeframes will make Medicaid consistent with their usual and customary business practices and reduce their burden.

Section 438.416(b) and (c) would set forth a standard for the minimum types of information an entity must record during the appeals process and how that information must be stored. This standard aligns with the standards in the private market. Most insurers offer more than one line of business, and therefore, we believe aligning record keeping standards will make Medicaid consistent with usual and customary business practices.

F. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit CMS' Web site at *www.cms.hhs.gov/Paperwork@cms.hhs.gov*, or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received on/by July 27, 2015.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

This proposed rule modernizes the Medicaid managed care regulations recognizing changes in the usage of managed care delivery systems since the release of the final rule in 2002. As Medicaid managed care programs have developed and matured in the intervening years, states have taken various approaches to implementing part 438. This has resulted in inconsistencies and, in some cases, less than optimal results. To improve consistency and adopt policies and practices from states that have proven the most successful, we propose revisions in this rule to strengthen beneficiary protections, support alignment with rules governing managed care in other public and private sector programs, strengthen actuarial soundness and the accountability of rates paid in the Medicaid managed care program, and implement statutory provisions issued since 2002.

According to the 2013 Actuarial Report on the Financial Outlook for Medicaid, total Medicaid outlays in federal FY 2012 exceeded $431 billion;

$250 billion, or 58 percent represented federal spending, and $181 billion, or 42 percent represented state spending.[19] States have continued to expand the use of managed care in the past decade, not only to new geographic areas but to more complex populations, including seniors, persons with disabilities, and those who need long-term services and supports. Today, the predominant form of managed care in Medicaid is capitated risk-based arrangements—virtually identical in structure and payment to arrangements in the private insurance market in many ways. Coordination and alignment with the private insurance market will improve operational efficiencies for states and health plans and improve the experience of care for individuals moving between insurance coverage options. Total Medicaid managed care spending (federal and state) exceeded $132 billion in 2013,[20] with expenditures rising annually as new beneficiaries and programs move into a managed care delivery system. It is CMS' responsibility to make sure these dollars are spent wisely, ensuring that there is adequate funding to support the delivery of required services to beneficiaries without wasting state and federal tax dollars. Additionally, the prevalence of MLTSS being delivered through a risk-based capitated system has increased significantly since the regulations were last published. Beneficiaries using MLTSS are among the most vulnerable, and often require enhanced protections to preserve health and welfare. This regulation would codify these necessary beneficiary protections in MLTSS. The changes we propose in this rule for rate setting, medical loss ratio, encounter data, and reporting, would support and reflect the increased efforts of states and health plans to provide more comprehensive, coordinated, and effective care while achieving better health outcomes.

Congress established CHIP in 1997 through the passage of the Balanced Budget Act (BBA) and reauthorized it in 2009 with the passage of the Children's Health Insurance Program Reauthorization Act (CHIPRA). Since CHIP was established, participation has grown steadily, and the rate of uninsured children has been reduced by half. The most recent data indicate that more than 87 percent of eligible children are enrolled in CHIP or Medicaid. Managed care has always been a large part of CHIP, because the program was established in an era of increased use of managed care in all health care sectors and the flexibility granted to states in administering the program. Many states enroll all or nearly all of their CHIP population in managed care plans. At the same time, CHIP has historically had few regulations related to the use of managed care.

When Congress reauthorized CHIP in 2009 in section 403 of CHIPRA, it applied a number of the Medicaid managed care provisions in section 1932 of the Act to CHIP. In response, we released two State Health Official (SHO) letters 09–008 and 09–013, issued on August 31, 2009 and October 21, 2009, respectively, which provided initial guidance on the implementation of section 403 of CHIPRA. (SHO #09–008 is available at *http://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SHO083109a.pdf.* SHO #09–013 is available at *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SHO102109.pdf.*) This proposed rule builds on that guidance. It would align CHIP managed care standards with those of the Marketplace and Medicaid, where practical, ensuring consistency across programs. Consistency has the benefit of creating efficiencies for both plans and beneficiaries, including operational efficiencies for plans from using similar rules and smoother transitions between programs for beneficiaries.

The BBA established quality standards for Medicaid managed care programs: A quality assessment and improvement strategy, and an external, independent review. While these standards initially applied only to MCOs, the application of several of them has spread to PIHPs (via the regulations at part 438, subparts D (Quality Assessment and Performance Improvement, effective on August 13, 2002 (67 FR 40989)) and E (External Quality Review, effective on March 25, 2003 (68 FR 3586)) and to CHIP managed care programs (per the CHIPRA). States that use a combination of managed care and other delivery systems are encouraged to use their quality strategies to develop a comprehensive quality plan across all delivery systems (as described in State Health Official letter entitled Quality Considerations in Medicaid and CHIP (SHO #13–007, available at *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SHO-13-007.pdf*)). Changes, in both MA and the private sector, related to performance measurement, quality rating systems, and private accreditation help to improve the health of beneficiaries while also controlling health care costs. Statewide comprehensive quality strategies, along with improvements to Medicaid and CHIP managed care quality, will give states additional tools to evaluate and improve the care received by beneficiaries.

For all of these reasons, the current regulatory framework is no longer the most appropriate or efficient to achieve program goals. We believe that it is necessary to modernize the Medicaid and CHIP managed care and quality regulations to support health care delivery system reform, improve population health outcomes, and improve the beneficiary experience in a cost effective and consistent manner in all states.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the 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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or

[19] *http://www.medicaid.gov/medicaid-chip-program-information/by-topics/financing-and-reimbursement/downloads/medicaid-actuarial-report-2013.pdf.*

[20] CMS, Financial Management Report—Base Payments, 2013.

the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rule is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that to the best of our ability presents the costs and benefits of this rule. The numbers presented in this RIA are rounded depending on the level of precision in the data used to generate them. Specifically, all COI costs are rounded to $0.1 million while transfers are rounded to the nearest $100 million. This difference also allows us to display the smaller numbers in the COI costs, which would reflect zero if rounded to the nearest $100 million.

Tables 3 and 4 show the overall estimates of the financial impact of this proposed rule in comparison to the status quo under the current regulatory framework. These tables and analyses use administrative burden estimates from the Paperwork Reduction Act documentation as well as any other quantifiable and qualitative benefits and costs when available. Table 3 divides the overall cost estimates into federal costs, state costs, and private sector costs with high and low estimates as appropriate. Table 4 divides the overall transfer estimates into federal and state transfers with high and low estimates as appropriate. Utilizing burden estimates from section IV of this proposed rule (COI) and estimated transfers, federal, state, and private sector costs and transfers were derived by applying the appropriate FMAP and the corresponding burdens in section IV of this proposed rule. For the revisions in part 438, we applied a weighted FMAP of 58.44 percent (weighted for enrollment) to estimate the federal share of private sector costs. This was done to account for private sector costs that are passed to the federal government through the managed care capitation rates. For part 457, we applied an enhanced FMAP of 93.9 for 2016 through 2019 and an enhanced FMAP of 71.5 for 2020 for both state and private sector costs. These represent the average CHIP FMAP in the respective years under current law. Federal CHIP funding is capped and is currently appropriated through 2017; therefore federal CHIP expenditures will not exceed the total allotments described in section 2104(a) of the Act.

Table 3 separates the overall costs by part 431, which represents comprehensive quality strategies; part 438, which represents Medicaid managed care; and part 457, which represents CHIP. As shown in Table 3, the total cost associated with this proposed rule is a cumulative $0.1 million in the first year for the revisions to part 431, a cumulative $86 million in the first year for revisions to part 438, and a cumulative $25.6 million in the first year for revisions to part 457, for a total cost of a cumulative $111.7 million for all revisions in the first year. Table 4 represents the overall transfer estimates for part 438 only, as parts 431 and 457 have no estimated transfers. As shown in Table 4, the total estimated transfers associated with this proposed rule range from a potential −$1 billion to a potential $300 million in the first year.

The COI costs estimated for some of the provisions are based on the number of enrollees. As such, as enrollment grows each year, the cost for these provisions will grow accordingly. For this analysis, we used the projected average enrollment growth rate for Medicaid of 3.3 percent [21] for Medicaid managed care enrollment to trend cost burdens. Recognizing the success that states have had enrolling eligible children in CHIP (more than 87 percent of eligible children enrolled in CHIP or Medicaid [22]) and the current prevalence of managed care in the program, we used a 3 percent growth rate for CHIP managed care enrollment. The burdens estimated for the quality components (proposed amendments to part 431 and part 438 subpart E) are not associated with enrollment, and therefore do not display any variable costs.

This RIA includes the administrative costs (wage and labor) related to implementing and operating a Medicaid managed care delivery system as well as non-administrative benefit and cost estimates when available. The burden estimates presented in section IV of this proposed rule provide the detail supporting the summary COI burden estimates presented in this RIA. As part of the costs considered outside of the COI, we included information technology and information systems costs, such as small system modifications or upgrades. However, we believe these costs are minimal and consistent with the nature of business in contracting and providing services to Medicaid and CHIP managed care enrollees. We also believe that many of these costs would fall under routine IT maintenance and upgrades. Therefore, we believe that these costs would have a negligible impact consistent with normal business practices.

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[21] *http://www.medicaid.gov/medicaid-chip-program-information/by-topics/financing-and-reimbursement/downloads/medicaid-actuarial-report-2013.pdf.*

[22] Genevieve M. Kenney, Nathaniel Anderson, Victoria Lynch. Medicaid/CHIP Participation Rates Among Children: An Update. September 2013. Available at *http://www.urban.org/sites/default/files/alfresco/publication-pdfs/412901-Medicaid-CHIP-Participation-Rates-Among-Children-An-Update.pdf.*

TABLE 3: Overall Federal, State, and Private Costs for Parts 431, 438, and 457 (in millions of dollars)

Part 431												
	2016		2017		2018		2019		2020		2016-2020	
	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High
Federal	$0.05	$0.05	$0.05	$0.05	$0.05	$0.05	$0	$0	$0	$0	$0.15	$0.15
State	$0.05	$0.05	$0.05	$0.05	$0.05	$0.05	$0	$0	$0	$0	$0.15	$0.15
Private	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Total Part 431	**$0.1**	**$0.1**	**$0.1**	**$0.1**	**$0.1**	**$0.1**	**$0**	**$0**	**$0**	**$0**	**$0.3**	**$0.3**
Part 438												
	2016[2]		2017		2018		2019		2020		2016-2020	
	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High
Federal[1]	$51.7	$51.7	$54.1	$54.1	$54.9	$54.9	$50.9	$50.9	$51.7	$51.7	$263.3	$263.3
State	$6.4	$6.4	$6.7	$6.7	$6.8	$6.8	$6.2	$6.2	$6.4	$6.4	$32.5	$32.5
Private	$27.9	$27.9	$29.1	$29.1	$29.6	$29.6	$27.4	$27.4	$27.9	$27.9	$141.9	$141.9
Total Part 438	**$86**	**$86**	**$89.9**	**$89.9**	**$91.3**	**$91.3**	**$84.5**	**$84.5**	**$86**	**$86**	**$437.7**	**$437.7**
Part 457												
	2016		2017		2018		2019		2020		2016-2020	
	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High
Federal[3]	$24	$24	$24	$24	$24.1	$24.1	$22.6	$22.6	$17.3	$17.3	$112	$112
State	$0.2	$0.2	$0.2	$0.2	$0.2	$0.2	$0.2	$0.2	$0.8	$0.8	$1.6	$1.6
Private	$1.4	$1.4	$1.4	$1.4	$1.4	$1.4	$1.3	$1.3	$6.0	$6.0	$11.5	$11.5
Total Part 457	**$25.6**	**$25.6**	**$25.6**	**$25.6**	**$25.6**	**$25.6**	**$24.1**	**$24.1**	**$24.2**	**$24.2**	**$125.1**	**$125.1**
Total Costs for Parts 431, 438, and 457												
	2016		2017		2018		2019		2020		2016-2020	
	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High
Total Part 431	$0.1	$0.1	$0.1	$0.1	$0.1	$0.1	$0	$0	$0	$0	$0.3	$0.3
Total Part 438	$86	$86	$89.9	$89.9	$91.3	$91.3	$84.5	$84.5	$86	$86	$437.7	$437.7
Total Part 457	$25.6	$25.6	$25.6	$25.6	$25.6	$25.6	$24.1	$24.1	$24.2	$24.2	$125.1	$125.1
Grand Total	**$111.7**	**$111.7**	**$115.6**	**$115.6**	**$117**	**$117**	**$108.6**	**$108.6**	**$110.2**	**$110.2**	**$563.1**	**$563.1**

[1]Includes federal costs based on a weighted FMAP of 58.44 percent.
[2]Estimates based on 2012 data.
[3]Includes federal costs based on an average FMAP of 93.9 for 2016-2019 and an average FMAP of 71.5 for 2020.

All state Medicaid programs receive a federal matching rate of at least 50 percent for administrative expenses and 50 to 73 percent (determined individually by state) for covered service expenses, with exceptions for

TABLE 4: Overall Federal and State Transfers for Part 438 (in millions of dollars)
***Parts 431 and 457 do not have transfers**

Part 438												
	2016		2017		2018		2019		2020		2016-2020	
	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High
Federal	-$600	$200	-$1,400	$400	-$2,000	$400	-$2,100	$500	-$2,300	$500	-$8,400	$2,000
State	-$400	$100	-$800	$300	-$1,200	$400	-$1,300	$400	-$1,400	$400	-$5,100	$1,600
Total Part 438	**-$1,000**	**$300**	**-$2,200**	**$700**	**-$3,200**	**$800**	**-$3,400**	**$900**	**-$3,700**	**$900**	**-$13,500**	**$3,600**

certain services and eligibility groups. State CHIP programs receive a higher federal funding rate, ranging from 88 to 100 percent for 2016 through 2019 and ranging from 65 to 82 percent for 2020; states receive the same federal funding rate for administrative expenses, but they are capped at 10 percent of a state's total CHIP expenditures. The Medicaid managed care plans are paid actuarially sound capitation rates to cover the costs of fulfilling their obligations under their contract. These rates are included in the expenditures by the state and subsequently submitted to CMS for federal matching payments at the state's assigned rate. This is reflected in Table 3 in the ''Private Sector'' row. State expenditures for external quality review (EQR) and EQR-related activities performed by EQROs for MCOs with contracts under section 1903(m) of the Act are eligible for a federal matching rate of 75 percent; EQR on other types of managed care entities or EQR-related activities conducted by non-EQROs are eligible for a 50 percent federal matching rate. CHIP EQR activities are considered administrative activities, which receive the CHIP federal funding rate, and count towards the administrative cap.

Table 5 shows the estimate of the impact for the COI costs of this proposed rule, divided into fixed and variable costs. Fixed costs are those which do not change with the number of enrollees while variable costs change with the number of enrollees.

TABLE 5: Overall Fixed and Variable Costs for Parts 431, 438, and 457 (in millions of dollars)

	Part 431				
	2016[2]	**2017**	**2018**	**2019**	**2020**
Fixed costs	$0.1	$0.1	$0.1	$0	$0
Variable costs	N/A	N/A	N/A	N/A	N/A
Part 431 Subtotal	**$0.1**	**$0.1**	**$0.1**	**$0**	**$0**
	Part 438				
	2016[2]	**2017**	**2018**	**2019**	**2020**
Fixed costs	$24.9	$24.9	$24.9	$16.7	$16.7
Variable costs[1]	$61.1	$65	$66.4	$67.8	$69.3
Part 438 Subtotal	**$86**	**$89.9**	**$91.3**	**$84.5**	**$86**
	Part 457				
	2016[2]	**2017**	**2018**	**2019**	**2020**
Fixed costs	$24.7	$24.7	$24.6	$23.1	$23.2
Variable costs[3]	$0.9	$1	$1	$1	$1
Part 457 Subtotal	**$25.6**	**$25.6**	**$25.6**	**$24.1**	**$24.2**
Total for Parts 431, 438, and 457	**$111.7**	**$115.6**	**$117**	**$108.6**	**$110.2**

[1]Utilizes the average enrollment growth rate as established in the 2013 Actuarial Report on the Financial Outlook for Medicaid: http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Financing-and-Reimbursement/Downloads/medicaid-actuarial-report-2013.pdf.
[2] Estimates based on 2012 data.
[3]Utilizes a 3 percent growth rate.

1. Cost Estimates by Guiding Principles

The principles discussed below guided the policy development and changes proposed in this rule. These guiding principles and proposed regulatory changes support the coordination and integration of health care, promote effective forms of information sharing, and require transparency on cost and quality information to support greater overall accountability in the Medicaid and CHIP programs. Detailed COI burden estimates can be found in section IV of this proposed rule. This section details

the significant COI costs and transfers related to benefits and costs associated with this proposed rule.

2. Setting Actuarially Sound Rates and Other Payment and Accountability Improvements

This guiding principle seeks to provide more data, analytical rigor, documentation, and transparency in the managed care rate-setting process and includes setting actuarially sound capitation rates and program integrity. The estimated first-year COI costs associated with the provisions under this guiding principle account for a cumulative $1 million of the total estimated first-year burden for the revisions to part 438 and part 457 (detailed burden estimates can be found in the COI section of this proposed rule at sections IV.D.4 and IV.D.5 for rates and IV.D.36 and IV.D.37 for program integrity).

The rule also proposes new requirements related to setting actuarially sound capitation rates in sections § 438.4 through § 438.7. Many of these requirements would codify current policy on developing capitation rates for Medicaid managed care plans. Other requirements set standards for actuaries developing the capitation rates, specify requirements for data and information that must be included in the actuarial certification of the rates, or describe the CMS process for reviewing and approving the rates. As such, we believe that many of these provisions are unlikely to have a direct effect on the actual capitation rates or future Medicaid expenditures. To the extent that these new standards or requirements do have an effect on capitation rates or Medicaid expenditures, we believe this could lead to increases in some cases and decreases in other cases in the capitation payment rates and Medicaid expenditures.

In particular, we believe that the combination of the new proposed requirements related to actuarial soundness and the proposed change to no longer allow states to certify rate ranges and to require states to certify specific capitation rates may have some financial impact. Currently, 40 states and the District of Columbia have at least one managed care program as part of their Medicaid program. Of these, 26 states and the District of Columbia currently certify rate ranges instead of rates for at least one managed care program in the state (Arkansas; California; Colorado; Delaware; District of Columbia; Georgia; Idaho; Indiana; Iowa; Kansas; Kentucky; Louisiana; Maryland; Massachusetts; Minnesota; Missouri; Nebraska; New Mexico; New York; North Carolina; North Dakota; Oregon; Pennsylvania; Tennessee; Utah; Virginia; and West Virginia). The certified rate ranges in many cases can be large. Based on our review of the most recent actuarial certifications in states that use rate ranges, the width of the rate range is 10 percent or smaller in 14 states (that is, the low end and the high end of the range are within 5 percent of the midpoint of the range), but in some states the ranges may be as wide as 30 percent (that is, the low end and the high end are within 15 percent of the midpoint of the range). In addition, most states tend to set the contracted capitation payment rates toward the lower end of the rate range.

For states that currently use relatively narrower rate ranges (which we would generally define as 10 percent or less), we believe that the states would be able to meet the proposed requirements and reasonably set rates that would be equivalent to those at the low end of the rate ranges (if the states were still able to certify a rate range). For states with relatively wider rate ranges (those that are greater than 10 percent), we believe that the states may not be able to set rates equivalent to the current low end of the rate range. In general, our opinion is that in cases where the rates would be more than 5 percent below the midpoint of the rate ranges it would be more difficult for a state to certify that rate as actuarially sound (and at the same time meet all of the other actuarial soundness requirements).

To estimate the high end of the range of the potential financial impact, we assumed that in states that had rate ranges wider than 10 percent and set rates at the low end of the rate range, that future Medicaid MCO, PIHP, and PAHP premiums would increase 2.5 percent (that is, roughly the average across all states of how much the low end of the rate range would need to increase to bring the width of the rate range to about 10 percent). We also included states for which the rate certification provided no information about the actual contracted capitation payment rates. For states with wide rate ranges but that paid rates at different points within the rate ranges, we assumed that the rates would increase by 1.25 percent (that is, half of the increase in rates for states that paid at the low end of the rate range). We assumed no impact on states with relatively narrower rate ranges (10 percent or less).

These changes increased projected Medicaid managed care expenditures by $3.6 billion from 2016 to 2020, or about 0.4 percent overall of about $1.3 trillion in projected Medicaid expenditures on MCOs, PIHPs, and PAHPs over the 5-year period. These estimates would be an increase of about 1.5 percent in costs in states assumed to be affected by this change. We believe that these estimates are a reasonable upper bound on the projected effect of these proposed changes.

In addition, we believe that there may be cases where these changes would reduce capitation rates and Medicaid expenditures. In particular, there are some states that make significant retroactive changes to the contracted rates at or after the end of the rating period. We do not believe that these changes are made to reflect changes in the underlying assumptions used to develop the rates (for example, the utilization of services, the prices of services, or the health status of the enrollee), but are used to provide additional reimbursements to the plans or to some providers. We believe that the proposed requirements for actuarial soundness and certifying the capitation rates would limit these types of changes and may result in some reduction in Medicaid expenditures.

To estimate the high end of the range of the potential financial impact, we assumed that in states that we are aware of that make these types of changes to the capitation rates, that an amount equal to 50 percent of the difference between paying MCOs, PIHPs, and PAHPs at the low end and the high end of the rate ranges would not be paid to the plans. These changes decreased projected Medicaid managed care expenditures by $11.0 billion from 2016 to 2020, or about 0.9 percent of about $1.3 trillion in projected expenditures on MCOs, PIHPs, and PAHPs over those 5 years. We believe that these estimates are a reasonable upper bound on the projected effect of these proposed changes.

Thus, we believe that the effects of these changes to Medicaid managed care actuarial soundness requirements and the requirement to certify the capitation rates could increase expenditures as much as $3.6 billion from 2016 to 2020 and could decrease expenditures as much as $11.0 billion from 2016 to 2020. We believe that these estimates reflect reasonable upper and lower bounds on the potential effect of these changes in the proposed regulation. Assuming that these changes in the regulation are effective mid-way through 2016, we estimate that the proposed changes related to actuarial soundness requirements and certifying the capitation rates would have the following effects as shown in Table 6.

TABLE 6: Projected Financial Effects (Transfers) of Actuarial Soundness Requirements, FY 2016-2020 (in millions of dollars)

Payer	2016	2017	2018	2019	2020	2016-2020
Low estimate						
Federal government	–$600	–$1,400	–$1,500	–$1,600	–$1,700	–$6,800
States	–$400	–$800	–$900	–$1,000	–$1,100	–$4,200
Total	–$1,000	–$2,200	–$2,400	–$2,600	–$2,800	–$11,000
High estimate						
Federal government	$200	$400	$400	$500	$500	$2,000
States	$100	$300	$400	$400	$400	$1,600
Total	$300	$700	$800	$900	$900	$3,600

It is possible that the impacts could be more or less than estimated here. More or fewer states may need to adjust capitation rates than we have assumed here. In particular, it is possible that states with relatively narrower ranges may decide that the capitation rates would still need to be higher than what would have been the low end of the rate range previously. We believe that states that use rate ranges as wide as 10 percent may still be affected by these changes. In addition, states may adjust their capitation rates to a greater or less extent than we have assumed here. These changes may also affect states that do not use rate ranges. While we believe that the proposed changes related to rate setting may be more likely to affect states that currently use relatively wide rate ranges, it is also possible that this may affect other states, including those that do not use rate ranges at all.

In addition, for states that historically have made significant changes to capitation rates within the rate ranges at the end or after the end of the rating period, those states may adjust their rate setting approaches as well. The payments might be closer to or farther from the final payments than we have estimated. Finally, these projections rely on the data, assumptions, and methodology used to develop the President's FY 2016 Budget projections for Medicaid. Changes in enrollment, health care costs, and the use of managed care plans within Medicaid may differ from these projections and may lead to greater or lesser Medicaid MCO, PIHP, and PAHP expenditures.

3. Program Integrity

Another aspect of this rule that we evaluated under this principle was enhancements to program integrity. We believe that many of these program integrity activities are currently already being performed by states and MCOs, PIHPs, and PAHPs. For program integrity activities that would be new or expanded under the proposed changes, there is very limited information on the effect that program integrity activities in general have on Medicaid expenditures. The lack of information is especially true for specific program integrity activities. While we believe these new activities may lead to some additional recoveries from plans, providers, or other individuals and may also deter entities from committing fraud or violating program requirements, it is difficult to determine the financial impacts of these activities and we believe that any financial impact is unknown. Therefore, we assume that the proposed changes are likely to have a negligible financial impact on future Medicaid expenditures. We invite comment on possible ways to quantify the costs and/or benefits associated with these proposed provisions.

4. Alignment With Other Insurers.

This guiding principle seeks to align Medicaid and CHIP managed care requirements with the Marketplace or MA to better streamline the beneficiary experience and to reduce operational burdens on health plans across publicly-funded programs and the commercial market. This guiding principle covers the regulatory topics of marketing, appeals and grievances, medical loss ratio, and standard contract provisions. As shown in Table 7, the COI costs associated with the provisions under this principle account for a cumulative $6 million in the first year for the revisions to part 438.

TABLE 7: Costs of Alignment with Insurers for Part 438 (in millions of dollars)

Medical Loss Ratio Standards[1]	2016	2017	2018	2019	2020
Federal	$2.6	$2.6	$2.6	$1.2	$1.2
State	$0	$0	$0	$0	$0
Private	$1.9	$1.9	$1.9	$0.9	$0.9
Appeals and Grievances[2]					
Federal	$0.9	$0.9	$0.9	$0.9	$0.9
State	$0	$0	$0	$0	$0
Private	$0.6	$0.7	$0.7	$0.6	$0.6
Total					
Federal	$3.5	$3.6	$3.6	$2.1	$2.1
State	$0	$0	$0	$0	$0
Private	$2.5	$2.5	$2.5	$1.5	$1.5
Grand Total	**$6**	**$6.1**	**$6.1**	**$3.6**	**$3.6**

[1] §438.8
[2] §§438.400-438.416

Similarly, as shown in Table 8, the COI costs associated with implementing the provisions under this principle account for a cumulative $11.6 million in the first year for the revisions to part 457.

TABLE 8: Costs of Alignment with Insurers for Part 457 (in millions of dollars)

Medical Loss Ratio Standards[1]	2016	2017	2018	2019	2020
Federal	$0.5	$0.5	$0.5	$0.2	$0.1
State	$0	$0	$0	$0	$0
Private	$0	$0	$0	$0	$0.1
Appeals and Grievances[2]					
Federal	$10.4	$10.4	$10.4	$10.3	$7.9
State	$0	$0	$0	$0	$0
Private	$0.7	$0.7	$0.7	$0.7	$3.1
Total					
Federal	$10.9	$10.9	$10.9	$10.5	$8
State	$0	$0	$0	$0	$0
Private	$0.7	$0.7	$0.7	$0.7	$3.2
Grand Total	**$11.6**	**$11.6**	**$11.6**	**$11.2**	**$11.2**

[1] §457.1205
[2] §457.1260

5. Medical Loss Ratio

As an increasing and more diverse set of Medicaid services are being delivered through managed care, good measurement systems are increasingly important to ensure that Medicaid funding is used prudently and that capitation rates are sufficiently based on the expenses associated with services. The implementation of a MLR is an integral part of the overall financial accountability aspects of the proposal and would align Medicaid and CHIP with the private health insurance market, as well as with MA. MLR reporting is a valuable tool to ensure that capitation rates for MCOs, PIHPs, and PAHPs are actuarially sound and adequately based on reasonable expenditures for covered services. Acknowledging that basis for proposing an MLR requirement, there are four benefits to having a common national standard for the calculation, reporting and use of MLR as we have proposed: (1) It will provide greater transparency for the use of Medicaid funding; (2) it will allow comparability across states and facilitate better rate setting; (3) it will facilitate better comparisons to MLRs in MA and the private health market; and (4) it will reduce the administrative burden on health plans by providing a consistent approach to ensuring financial accountability for managed care plans working in multiple product lines and/or operating in multiple states. The proposed provisions in §§ 438.4, 438.5, 438.8, 457.1203 and 457.1205 require MCOs, PIHPs, and PAHPs to calculate, report, and use a MLR in the development of capitation rates. The estimated first-year COI cost for the proposed provisions in part 438 is a cumulative $4.5 million (detailed burden estimates can be found in the COI section of this proposed rule at section IV.D.6 for MLR). The total estimated first-year COI cost associated with implementing the proposed MLR provisions of part 457 is a cumulative $0.5 million.

This rule proposes new requirements that would require the states to calculate and report the medical loss ratios (MLRs) for Medicaid MCOs, PIHPs, and PAHPs in § 438.4 and § 438.5, and to add new § 438.8 and § 438.74, as well as incorporate an MLR assumption in the rate setting process. These changes, however, do not require that states assess any financial penalties on MCOs, PIHPs, and PAHPs that do not meet a minimum MLR. We will encourage states to adopt minimum MLRs or to develop similar financial arrangements to incentivize better plan performance; however, as states are already permitted to implement a minimum MLR or similar standards and some choose not to do so, we believe that this rule is unlikely to encourage more states to do so and therefore is unlikely to have any direct financial impact on Medicaid expenditures for MCOs, PIHPs, and PAHPs; however, we believe that there is the potential for some financial impacts when considering the proposed MLR requirements and the actuarial soundness standards requirements.

We do not collect data or information on the MLRs of Medicaid MCOs, PIHPs, and PAHPs, nor do we collect the data or information necessary to calculate the

loss ratios. Milliman has published a series of annual research papers that review Medicaid MCO performance, including data on MLRs. We have reviewed the most recent research papers covering 2011, 2012, and 2013 for our review of the potential impacts of the proposed regulation related to MLRs (''Medicaid Risk-Based Managed Care: Analysis of Financial Results for 2011,'' Palmer and Pettit, July 2012; ''Medicaid Risk-Based Managed Care: Analysis of Financial Results for 2012,'' Palmer and Pettit, June 2013; and ''Medicaid Risk-Based Managed Care: Analysis of Financial Results for 2013,'' Palmer and Pettit, June 2014). These studies provide an analysis of Medicaid managed care plans, including loss ratios, covering 35 states and territories, including the District of Columbia and Puerto Rico, and up to 167 managed care plans.

From 2011 to 2013, the mean MLR varied between 85.5 percent and 87.9 percent, with an average of 87.0 percent over the 3-year period (weighted by the number of plans reporting each year). A significant percentage of plans experienced loss ratios below the 85-percent target noted in this proposed rule. In each year, 10 percent of plans experienced loss ratios below 78.0 percent to 79.4 percent, and 25 percent of plans experienced loss ratios below 82.6 percent to 83.6 percent. Thus, we would expect a substantial number of plans would likely not meet a minimum loss ratio of 85 percent each year.

We fit a normal distribution to the MLRs based on the average loss ratios at each percentile shown in the Milliman reports (10th, 25th, 50th, 75th, and 90th) for 2011, 2012, and 2013. This suggested that between 37 percent and 39 percent of plans would have loss ratios equal to or less than 85 percent over this period. Assuming that the distribution of loss ratios is not affected by the size of the MCO or the MCO's total revenue (in general, the Milliman reports did not suggest any apparent correlation), we calculate that if all states enforced a minimum MLR of 85 percent and if MCOs with smaller loss ratios had to return revenue such that the effective loss ratio would be equal to 85 percent, that MCOs on average would return 1.5 percent to 1.9 percent of total revenue. (This does not account for any impact of the credibility adjustment proposed in the regulation.) To the extent that smaller MCOs, PIHPs, and PAHPs would receive a credibility adjustment and thus effectively lower the minimum MLR standard for those plans, the percentage of total revenue returned may be less than estimated.

In 2013, the sum of MCO, PIHP, and PAHP payments was $132 billion (CMS, Financial Management Report—Base Payments);[23] therefore, we estimate that if a minimum MLR had been enforced for each MCO, PIHP or PAHP in all states in 2013, that between $2.0 billion and $2.5 billion would have been returned by MCOs, PIHPs, and PAHPs to the federal government and the states in that year.

As of 2013, we found, based on an internal review, 12 states that had requirements about a minimum MLR; of those, 6 enforced financial penalties for MCOs or other plans that did not have loss ratios at least equal to the minimum MLR. Those 6 states accounted for about 11 percent of Medicaid MCO, PIHP, and PAHP expenditures in 2013. Relatedly, a study by the Kaiser Family Foundation found that as of 2010 there were 11 states that had a minimum MLR requirement for Medicaid MCOs, PIHPs, or PAHPs (''A Profile of Medicaid Managed Care Programs in 2010: Findings from a 50-State Survey,'' Gifford, Smith, Snipes, and Paradise, September 2011).

There is significant variation in the standards currently in place, as states may have different methods of calculating the MLRs (for example, whether or not they include certain costs as medical expenses or losses, and whether or not they make certain adjustments to plans' revenues) and have different minimum MLRs (although all such minimums fell between 80 percent and 88 percent). In addition, many states that implemented the eligibility expansion under the Affordable Care Act to all adults up to age 65 with household incomes of 138 percent or less included a minimum MLR requirement or a similar risk-sharing arrangement in its contracts with MCOs, PIHPs, and PAHPs for 2014. These currently existing requirements and standards may have some effect on the potential impact of the proposed changes.

For the purpose of illustrating the potential impact of these changes in the regulation, we have developed estimates assuming that all states would require a minimum MLR. If all states implemented the 85 percent minimum MLR requirement that is required to be calculated in the proposed regulation, we estimate that the federal government would collect about $7 billion to $9 billion between 2018 and 2020 and the states would collect about $4 billion to $5 billion over the 3-year period (although we note (1) the loss ratio in Medicaid would not be measured over 3 years like the MLR for QHPs; and (2) the first year an MCO, PIHP, or PAHP would have to refund Medicaid would be 2018). This calculation also accounts for states that already have a minimum loss ratio requirement in place. This amount would account for about 1.3 percent to 1.7 percent of projected MCO, PIHP, and PAHP expenditures.

We assume that this rule would not lead more states to implement an enforceable, minimum MLR; we therefore conclude that there would be no direct financial impact of the MLR provisions of the proposed rule.

Considering the proposed MLR requirements and the proposed changes to the requirements for actuarial soundness in § 438 (a)(7) that requires rates to be developed in such a way that the MCO, PIHP, or PAHP would reasonably achieve an MLR of at least 85 percent for the rate year, we believe it is possible that collecting and reporting MLRs for each MCO, PIHP, or PAHP and additional oversight of the rate setting process may lead states to make adjustments to setting capitation rates in the future. For example, if this additional information led a state to realize that the loss ratios for the MCOs, PIHPs, or PAHPs were consistently higher than or lower than expected, the state may adjust future rates lower or higher. We believe that there may be cases that lead to rate increases and other cases that lead to rate decreases relative to what the rates otherwise would have been.

Because the minimum MLR would not be enforced with a penalty under this proposed rule, the financial impacts would likely be significantly less than the estimates provided earlier. We believe that it is likely that any encouragement or oversight by CMS that would lead states to adjust rates would be less effective than implementing financial requirements on MCOs, PIHPs, and PAHPs that do not meet the minimum MLR. In addition, we believe that in many states there may only be one plan or a few plans which would not meet the minimum MLR in a given year (or conversely, one plan or a few plans which would have unusually high MLRs). In those cases, relatively low or high MLRs may be due in large part to the plans' own ability to manage costs (including their ability to manage utilization and costs), and not necessarily the result of the capitation rates being set too high or too low overall. Furthermore, some plans may only have MLRs below the minimum in a single year instead of more regularly; in those cases, while there would be a financial recovery if the minimum MLR

[23] CMS, Financial Management Report—Base Payments, 2013.

was required, it is less likely that there would be longer-term changes to the capitation rates as a result of that one year's experience.

Using a similar methodology as described previously to estimate the potential impact if all states were to require a minimum MLR of 85 percent, we have estimated what the effects of reporting the MLR and the other actuarial soundness requirements would be on Medicaid payments for MCOs, PIHPs, and PAHPs. Instead of calculating the amount of payments that would be returned if a minimum MLR of 85 percent was required, we have measured the amount of payments that would be returned for plans with MLRs below 82 percent, and assumed that the indirect effects of these proposed changes would be equal to 50 percent of that amount. We have assumed for plans with MLRs somewhat below 85 percent (which we defined here to be between 82 and 85 percent) that the states may not need to make significant adjustments to rate setting. For plans with MLRs further below 85 percent (82 percent or less), we assumed that these proposed changes would likely lead to decreases in future rates and payments below what would have otherwise occurred; however, we also assumed that the rates and payments would still have been adjusted by the states, as they would have a financial incentive not to significantly overpay the managed care plans. The percentage of all MCO, PIHP, and PAHP payments that would be paid from the plans to the federal government and the states for plans under these assumptions is estimated to be between 0.35 and 0.5 percent.

Similarly, we calculated the amount of additional payments that would need to be made for plans with high MLRs, which we assumed to be 95 percent or greater. In these cases, we believe that the plans may have a higher likelihood of experiencing a loss. The Milliman reports found that between 2011 and 2013 that 25 percent of all plans had MLRs above 90.0 to 91.9 percent, and that 10 percent of plans had MLRs above 96.6 to 97.3 percent. We believe that in the cases that the states may adjust future capitation rates and payments to be higher than they otherwise would have been, and assumed that these adjustments would equal 50 percent of the difference between a MLR of 95 percent and the actual MLR. We estimated that the percentage of all MCO, PIHP, and PAHP payments would be increased between 0.1 and 0.2 percent due to these changes.

The net effect of these changes is estimated to be a decrease in MCO, PIHP, and PAHP payments of about 0.2 to 0.3 percent. Between 2018 and 2020, a 0.3-percent decrease in MCO, PIHP, and PAHP expenditures is projected to be a reduction of $1.6 billion in federal expenditures and of $0.9 billion in state expenditures. We believe that this is a reasonable lower bound of the effect of these proposed changes. We believe that a reasonable upper bound of these estimates would be $0, assuming that the changes led to no financial impact. These estimates are shown in Table 9 below.

TABLE 9: Projected Financial Effects (Transfers) of Medical Loss Ratio and Actuarial Soundness Requirements, FY 2016-2020 (in millions of dollars)

Payer	2016	2017	2018	2019	2020	2016-2020
Low estimate						
Federal government	–$0	–$0	–$500	–$500	–$600	–$1,600
States	–$0	–$0	–$300	–$300	–$300	–$900
Total	–$0	–$0	–$800	–$800	–$900	–$2,500
High estimate						
Federal government	$0	$0	$0	$0	$0	$0
States	$0	$0	$0	$0	$0	$0
Total	$0	$0	$0	$0	$0	$0

There is a significant amount of uncertainty in these estimates beyond whether or not states would elect to implement an enforceable minimum MLR requirement. We have not accounted for the impact of the credibility adjustment. States and plans may also adjust their behavior as a result of the minimum MLR requirements; for example, states may set capitation payment rates differently to target certain loss ratios, and plans may make changes to how they manage health care costs and utilization for their enrollees. These changes may lead to differences in future expenditures for MCO, PIHP, and PAHP expenditures,

and thus the actual experience may differ from our estimates.

In addition, it is not clear that the reports we relied on measure MLR the same way as is proposed in the regulation. To the extent that there are differences, the actual range and distribution of MLRs among MCOs, PIHPs, and PAHPs that would be measured under the proposed regulation may be different than as shown in the studies (for example, if there are expenditures that would be considered medical losses under the proposed regulation but were not considered medical losses in the Milliman studies). This could lead to the actual effects of the MLR and actuarial soundness requirements being different than estimated here. In addition, it is possible that the effects of the proposed actuarial soundness and certification requirements may capture some of the same effects as estimated here; however, we have not made any adjustments to reflect any potential interaction between the two sets of changes.

Moreover, the extent of and the effectiveness of CMS' and states' efforts to adjust future capitation rates to target certain MLRs are difficult to predict. How CMS and the states respond to these changes would likely have a large bearing on the effect that these sections of the proposed regulation have on future Medicaid expenditures. Finally, these projections rely on the data, assumptions, and methodology used to develop the President's FY 2016 Budget projections for Medicaid. Changes in enrollment, health care costs, and the use of managed care plans within Medicaid may differ from these projections and may lead to greater or lesser Medicaid MCO, PIHP, and PAHP expenditures.

6. Appeals and Grievances

Proposed changes to the appeals and grievances provisions in §§ 438.400 through 438.416 and § 457.1260 focus on creating state and health plan processes that are consistent across product lines (that is, MA, Medicaid, CHIP, and qualified health plans). Medicaid currently differs from MA and the qualified health plans in several key ways and these differences hinder a streamlined grievance and appeals process across the public and commercial managed care sectors, and creates unnecessary administrative complexity for health issuers participating across product lines. Our proposed revisions will allow enrollees to better understand the grievance processes and receive a resolution of their grievances and appeals more quickly. We believe this will be a tremendous benefit to families that have some family members eligible for Medicaid and other family members eligible for marketplace coverage; enrollees that change between Medicaid and the qualified health plans due to life changes that affect eligibility; and enrollees that are dually eligible for Medicaid and Medicare. We believe consistency and quicker resolution of issues will not only make the enrollee more comfortable using the grievance system, but also confident that there is benefit in utilizing these systems when needed. Health plans have indicated that alignment of these provisions would reduce operational burden for those that operate across product lines and in different states as it would enable them to create and implement one set of uniform processes and procedures. A significant portion of the burden associated with this principle is the result of the proposal that Medicaid non-NEMT PAHPs comply with the same standards as MCOs and PIHPs. This proposed change will require non-NEMT PAHPs to develop a compliant grievance system, which will generate some one-time burdens, but we believe it is important for enrollees to have an avenue within these entities to raise and receive resolution to their grievances and appeals. The total estimated first-year COI costs for requiring Medicaid non-NEMT PAHPs to meet the same standards as MCOs and PIHPs and provide due process to beneficiaries through provisions in part 438 is a cumulative $1.5 million (detailed burden estimates can be found in the COI section of this proposed rule at sections IV.D.31 through IV.D.35 for appeals and grievances). We are also proposing to apply most of the Medicaid grievance regulations to CHIP MCOs, PIHPs, and PAHPs. The total estimated first-year COI costs associated with implementing the proposed grievance provisions of part 457 under this principle is a cumulative $11.1 million.

7. Allowing Payment for Institution of Mental Disease for Inpatient Psychiatric Services as an In Lieu of Service

The proposed regulation would allow MCOs and PIHPs, to pay institutions of mental disease (IMDs) using funds received from Medicaid to provide services to their beneficiaries as an in lieu of service, and sets requirements about how to consider the utilization and costs of covered services rendered in an IMD in developing the capitation rates. At this time, we do not have sufficient data to develop an estimate of the impact of these changes in the proposed regulation.

We do not know how many states currently allow plans to use IMDs to provide inpatient psychiatric services as an in lieu of service, nor do we collect data on the utilization and cost of such arrangements paid by Medicaid MCOs and PIHPs. We are aware that some states allow MCOs or PIHPs to use an IMD as a substitute provider for covered services. However, we do not know how many states currently permit this practice. The information cannot be determined from the contracts between the states and MCOs or PIHPs. States cannot require a managed care plan to use in lieu of services, and consequently, contracts do not include specific provisions for these services through an IMD. Likewise, we do not collect data on the utilization and cost of IMD services paid by MCOs or PIHPs.

There are two key potential financial impacts related to these changes. First, to the extent that inpatient psychiatric services rendered in an IMD are more cost-effective than the inpatient acute hospital setting, there is the potential for some reduction in expenditures; however, as the proposed regulation allows states to cover inpatient services in an IMD, while the preamble explains that prices for covered inpatient services rendered in an IMD cannot be used to determine the capitation rates, we believe that any reduction in expenditures for the federal government and the states is likely to be negligible. Second, these changes may encourage more states to cover mental health and substance abuse in IMDs as in lieu of services within the managed care plans. Because federal Medicaid payments are otherwise not permitted for persons in IMDs, allowing IMDs as a substitute setting for covered services may lead to an increase in federal Medicaid expenditures; as federal Medicaid outlays are not permitted for adults in IMDs, this change may lead to more costs eligible for federal matching funds that would have otherwise been deferred. It is not clear how much this proposed provision would incentivize states to allow plans to provide services in IMDs as in lieu of services. Similarly, it is unknown the extent to which this provision would lead states to move mental health and substance abuse services from the FFS program to managed care, although we do not believe that this provision would be the primary impetus for states to make a change from FFS to managed care. Given the lack of data and program information, it is not possible to develop credible estimates of the impacts of either of these effects or to determine if

a net increase or a net decrease in expenditures is more likely.

8. Beneficiary Protections

This guiding principle seeks to protect beneficiaries from harm and includes enrollment and disenrollment; beneficiary support system; continuation of benefits pending appeal; authorization of services; continued services and coordination of care; managed long-term services and supports; and stakeholder engagement. As the use of managed care to deliver Medicaid benefits has grown, so has the inclusion of more vulnerable populations into managed care. These new populations include persons with disabilities, individuals with behavioral health needs, and beneficiaries needing long-term services and supports. The unique needs and vulnerability of these newer populations heightens the need for added beneficiary protections and thus, prompted the proposed revisions to the regulations. As shown in Table 10, the COI costs associated with the provisions under this principle account for a cumulative $50.2 million in the first year for the revisions to part 438 (detailed burden estimates can be found in the COI section of this proposed rule at sections IV.D.10 and IV.D.17 for coordination/continuity of care and IV.D.18 for authorization of services).

TABLE 10: Costs of Beneficiary Protections for Part 438 (in millions of dollars)

Coordination/Continuity of Care[1]	2016	2017	2018	2019	2020
Federal	$28.9	$29.6	$30.4	$31.1	$31.9
State	$0.9	$0.9	$0.9	$0.9	$1
Private	$19.9	$20.4	$20.9	$21.5	$22
Authorization of Services[2]					
Federal	$0.1	$0.1	$0.1	$0	$0
State	$0	$0	$0	$0	$0
Private	$0.1	$0.1	$0.1	$0	$0
Other[3]					
Federal	$0.2	$0.2	$0.2	$0.1	$0.2
State	$0.1	$0.2	$0.2	$0.1	$0.1
Private	$0	$0	$0	$0	$0
Total					
Federal	$29.2	$29.9	$30.7	$31.2	$32.1
State	$1	$1.1	$1.1	$1	$1.1
Private	$20	$20.5	$21	$21.5	$22
Grand Total	**$50.2**	**$51.5**	**$52.8**	**$53.7**	**$55.2**

[1] §438.62, §438.208
[2] §438.210
[3] §438.54, §438.70, §438.71, §438.110

Similarly, as shown in Table 11, the COI costs associated with implementing the provisions under this principle account for a cumulative $12.1 million in the first year for the revisions to part 457.

TABLE 11: Costs of Beneficiary Protections for Part 457 (in millions of dollars)

Continued services to enrollees[1]	2016	2017	2018	2019	2020
Federal	$0.4	$0.5	$0.5	$0.2	$0.3
State	$0	$0	$0	$0	$0
Private	$0	$0	$0	$0	$0.1
Coordination/Continuity of Care[2]					
Federal	$7.8	$7.8	$7.8	$7.8	$5.9
State	$0	$0	$0	$0	$0.1
Private	$0.5	$0.5	$0.5	$0.5	$2.3
Authorization of Services[3]					
Federal	$3	$3.1	$3.2	$3.3	$2.6
State	$0	$0	$0	$0	$0
Private	$0.2	$0.2	$0.2	$0.2	$1
Enrollment[4]					
Federal	$0.2	$0.2	$0.2	$0.2	$0.1
State	$0	$0	$0	$0	$0.1
Private	$0	$0	$0	$0	$0.1
Total					
Federal	$11.4	$11.6	$11.7	$11.5	$8.9
State	$0	$0	$0	$0	$0.2
Private	$0.7	$0.7	$0.7	$0.7	$3.5
Grand Total	**$12.1**	**$12.3**	**$12.4**	**$12.2**	**$12.6**

[1] §457.1216
[2] §457.1230(c)
[3] §457.1230(d)
[4] §457.1210

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9. Coordination and Continuity of Care

The provisions for coordination and continuity of care are in § 438.62 and § 438.208. Under current regulations, these sections focus only on primary and acute medical care, which is not appropriate or consistent with the needs of people with disabilities, frail elders, and other LTSS populations. These populations rely heavily on less traditional services, such as support services for work, community activity access, and assistance with activities of daily living. For example, people with dementia may prefer and be able to live in the community with personal care assistance, memory aids, and alerting systems, but may not be able to identify and notify a care coordinator in situations of neglect or abuse. A young adult with an intellectual disability may be able to work with supports in place, but be at risk of harm if transportation falls through or a support worker does not show up for a scheduled time. These populations often require heightened

levels of monitoring and oversight by the care coordinator to ensure that they are able to fully access the services and supports needed to thrive in the community and to be sure that risks of harm or abuse are mitigated. Additionally, many of the providers for LTSS are small businesses and unaccustomed to working with managed care plans and care coordinators can be the bridge to establishing and building a productive relationship with these providers to best meet enrollees' needs.

The proposed regulations would address these enhanced care coordination needs by proposing provisions to strengthen the role of care coordinators who help beneficiaries transition from providers and services available through their current delivery system to providers and services available through a managed care plan. Care coordinators can help enrollees with finding specialty providers, understanding how the managed care program works, setting appointments, verifying delivery of services, and reminding enrollees of their appointments. The proposed regulations would also be strengthened to ensure that individuals with LTSS needs complete an accurate and timely person-centered assessment and service planning process with more frequent monitoring to assist beneficiaries in fully utilizing services. The proposed changes to these provisions are designed to enable people with disabilities and LTSS enrollees to live, work, and participate in the setting of their choice more safely, effectively, and with fewer lapses in care. Additionally, we propose to enhance existing requirements for coordination and continuity of care when enrollees move between plans or programs. While this has always been a requirement in part 438, we are aware of gaps in some states' and health plans' implementation for the LTSS population.

Behavioral health, substance use disorders, and institutional services are the most common services that managed care enrollees receive through FFS; coordinating these services with the managed care services is crucial to comprehensive care management. Enrollees receiving behavioral health or substance use treatment on a frequent, sometimes daily, basis are at high risk for emergency department visits or setbacks to their recovery if they experience a disruption in their services. The added protections provided by the proposed changes would ensure that enrollees, particularly those with complex health needs, experience smoother transitions, have fewer incidents of abuse or neglect, are able to retain the ability to live in their communities and have fewer emergency department visits or admissions. For enrollees receiving ongoing care and LTSS, lapses in care can trigger acute events and even be life threatening. Putting additional protections in place to prevent such occurrences is critical to enrollees' health outcomes. Care coordinators can help enrollees in these situations with finding appropriate providers, understanding how the managed care program works, setting appointments, and ensuring that appropriate authorizations are in the system to facilitate claims payment.

While we believe that the benefits of care coordination have a significant positive impact on the quality of life, consumer experience, and health outcomes for enrollees, we acknowledge that the activities that would bring about these positive impacts will likely generate costs. From an administrative perspective, the proposed provisions in § 438.62 have an estimated first-year COI cost of a cumulative $3.5 million, and the proposed provisions in § 438.208 have an estimated first-year COI cost of a cumulative $46.2 million (detailed burden estimates can be found in the COI section of this proposed rule at sections IV.D.10 and IV.D.17, respectively). In general, we expect that most of the activities that would be required under the proposed regulation are already being provided in some form by the state Medicaid program or by their MCOs, PIHPs, and PAHPs. We anticipate little to no new impacts in practice or in expenditures on activities already occurring with existing populations and benefits. However, we believe there is a greater likelihood that the proposed changes in the regulation specific to MLTSS could lead to new or additional care coordination expenditures. There are currently 20 states that use MLTSS. Unfortunately, there is very limited data available to determine the potential impact of this section of the proposed regulation. We do not collect consistent or validated cost data on Medicaid managed care encounters or administrative costs and, therefore, it is not possible to determine the amount of new expenditures for MCOs, PIHPs, and PAHPs to provide particular services or to serve particular enrollees. In any managed care program, we would generally expect care coordination expenditures to be a notable portion of MCO, PIHP, and PAHP administrative costs. Milliman has published studies [24] on the financial performance of Medicaid managed care plans that contains data on administrative costs for plans. These studies provide an analysis of Medicaid managed care plans covering 35 states and territories, including the District of Columbia and Puerto Rico, and up to 167 managed care plans. According to these studies, the average ratio of administrative expenditures to plan revenues ranged from 11.4 percent to 12.1 percent between 2011 and 2013. We believe that care coordination costs would likely be some fraction of that percentage, but are not able to determine the specific proportion. Given that administrative costs may cover a range of activities, we believe that it is most likely that care coordination costs are likely between 1 and 3 percent of plan revenue.

Unfortunately, there is also little data or research available on the amount of care coordination expenditures provided by MCOs, PIHPs, or PAHPs and the effectiveness of care coordination. Some studies have found that care coordination may lead to reductions in preventable inpatient readmissions and costs related to screening, testing, and evaluation. Studies [25] of transitional care models have found that they may reduce hospital readmissions while other demonstrations have found that care coordination has had some success in reducing hospitalizations and specialist visits [26]). Conversely, there are other studies [27] that have shown that care coordination may not have a significant effect on health care expenditures; for example, a study of one Medicare demonstration showed that most care coordination programs did not have a significant effect on the costs or the quality of care, and even successful programs were not able to achieve

[24] ''Medicaid Risk-Based Managed Care: Analysis of Financial Results for 2011,'' Palmer and Pettit, July 2012; ''Medicaid Risk-Based Managed Care: Analysis of Financial Results for 2012,'' Palmer and Pettit, June 2013; and ''Medicaid Risk-Based Managed Care: Analysis of Financial Results for 2013,'' Palmer and Pettit, June 2014.

[25] (''Estimated Federal Savings Associated with Care Coordination Models for Medicare-Medicaid Dual Eligibles,'' Thorpe 2011.

[26] (''Effects of Primary Care Coordination on Public Hospital Patients,'' Schillinger, Bibbins-Domingo, Vranizan, Bacchetti, Luce, and Bindman, Journal of General Internal Medicine, December 2001.

[27] (''Effects of Care Coordination on Hospitalization, Quality of Care, and Health Care Expenditures Among Medicare Beneficiaries,'' Peikes, Chen, Schore, and Brown, *The Journal of the American Medical Association,* February 2009; ''Six Features of Medicare Coordinated Care Demonstration Programs That Cut Hospital Readmissions of High-Risk Patients,'' Brown, Peikes, Peterson, Schore, and Razafindrakoto, *Health Affairs,* June 2012.

savings large enough to offset care coordination costs.

It should be noted that these studies and most other studies available have examined the effects of care coordination on hospitalizations and utilization of physician services on general Medicaid and/or Medicare populations; we are not aware of any studies or research that focuses specifically on the impact of care coordination on beneficiaries who are using long-term services and supports. To the extent that care coordination may be more likely to affect hospital and physician service costs and that many Medicaid enrollees receiving long-term services and supports are also enrolled in Medicare, any financial impact of care coordination may be more likely to affect Medicare rather than Medicaid.

While we do not collect the amount of managed care capitation payments or expenditures in such a way that the amount paid for managed long-term care services can be determined, we estimate about 38 percent of total Medicaid managed care expenditures were provided for aged and disabled enrollees in 2013 ($50 billion of $132 billion), and we expect a significant amount of those expenditures covered acute care services. Thus, the potential amount of expenditures on long-term services and supports under Medicaid managed care programs is expected to be relatively small compared to the rest of the program. At this time we believe a reasonable estimate of the financial impact of the proposed changes to care coordination requirements under the regulation is that there would be a net impact of $0. We believe that the expected increase in care coordination costs is likely to be small and that the effect of those activities on overall health benefit expenditures would be limited. The effect on overall expenditures would vary significantly depending on how successfully the managed care plans implement and/or enhance their current coordination efforts. We expect that provisions proposed in this rule related to setting actuarially sound rates, performance reporting, and encounter data reporting would enable more robust analysis of the effects of care coordination and transition efforts on expenditures in the future. We invite comment on possible ways to further quantify the costs and/or benefits associated with these proposed provisions.

We propose to apply some of the Medicaid beneficiary protections to CHIP, specifically the requirements in § 438.62, § 438.208, and § 438.210. We believe these protections will ensure that enrollees, particularly those with complex health needs, experience smoother transitions, and have fewer emergency department visits or admissions. The proposed provisions in § 438.62, § 438.208, and § 438.210 associated with implementing the beneficiary protection provisions of part 457 have an estimated first-year COI cost of a cumulative $12.1 million.

10. Modernizing Regulatory Requirements

This guiding principle seeks to incorporate the numerous advancements in state activities, health plan practices, and federal oversight interests since the inception of part 438. This guiding principle covers the regulatory topics of network adequacy and accessibility of services; quality measurement and improvement; state monitoring standards; information standards; primary care case management; choice of managed care plans; non-emergency transportation; and state plan standards. As shown in Table 12, the COI costs associated with the provisions under this principle account for a cumulative $28.3 million in the first year for the revisions to part 438 (detailed burden estimates can be found in the COI section of this proposed rule at section IV.D.7 for information standards and sections IV.D.21 through IV.D.30 for quality framework).

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TABLE 12: Costs of Modernizing Regulatory Requirements for Part 438 (in millions of dollars)

Information Standards[1]	2016	2017	2018	2019	2020
Federal	$0.5	$2	$2.1	$1.2	$1.2
State	$0	$0	$0	$0	$0
Private	$0.4	$1.4	$1.5	$0.8	$0.9
Quality Measurement and Improvement[2]					
Federal	$14.4	$14.4	$14.4	$12.6	$12.6
State	$9.1	$9.1	$9.1	$8	$8
Private	$3.7	$3.7	$3.7	$3.3	$3.3
Other[3]					
Federal	$0.1	$0.1	$0.1	$0.1	$0.1
State	$0.1	$0.1	$0.1	$0.1	$0.1
Private	$0	$0	$0	$0	$0
Total					
Federal	$15	$16.5	$16.6	$13.9	$13.9
State	$9.2	$9.2	$9.2	$8.1	$8.1
Private	$4.1	$5.1	$5.2	$4.1	$4.2
Grand Total	**$28.3**	**$30.8**	**$31**	**$26.1**	**$26.2**

[1] §438.10
[2] Subpart E, Quality Framework and External Quality Review
[3] §438.66, §438.68, §438.207

Similarly, as shown in Table 13, the COI costs associated with implementing the provisions under this principle account for a cumulative $0.1 million in the first year for the revisions to part 431.

TABLE 13: Costs of Modernizing Regulatory Requirements for Part 431 (in millions of dollars)

Quality Measurement and Improvement[1]	2016	2017	2018	2019	2020
Federal	$.05	$.05	$.05	$0	$0
State	$.05	$.05	$.05	$0	$0
Private	$0	$0	$0	$0	$0
Grand Total	**$0.1**	**$0.1**	**$0.1**	**$0**	**$0**

[1]Subpart I, Part 321

Similarly, as shown in Table 14, the COI costs associated with implementing the provisions under this principle account for a cumulative $4.1 million in the first year for the revisions to part 457.

TABLE 14: Costs of Modernizing Regulatory Requirements for Part 457 (in millions of dollars)

Information Standards[1]	2016	2017	2018	2019	2020
Federal	$0.7	$0.7	$0.8	$0.2	$0.1
State	$0	$0	$0	$0	$0
Private	$0	$0	$0	$0	$0.1
Quality Measurement and Improvement[2]					
Federal	$3.1	$3.1	$3.1	$2.6	$2
State	$0.1	$0.1	$0.1	$0.1	$0.5
Private	$0.1	$0.1	$0.1	$0.1	$0.3
Other[3]					
Federal	$0.1	$0.1	$0.1	$0.1	$0.1
State	$0	$0	$0	$0	$0
Private	$0	$0	$0	$0	$0
Total					
Federal	$3.9	$3.9	$4	$2.9	$2.2
State	$0.1	$0.1	$0.1	$0.1	$0.5
Private	$0.1	$0.1	$0.1	$0.1	$0.4
Grand Total	**$4.1**	**$4.1**	**$4.2**	**$3.1**	**$3.1**

[1] §457.1207
[2] §457.1240, §457.1250
[3] §457.1218, §457.1230(b)

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The provision of information to potential enrollees by the state and to enrollees by the managed care plans has always been a requirement in § 438.10. However, we have proposed changes to this section to better organize and clarify the standards for states and managed care plans. These changes are necessary, and important, since the information provided to potential and current enrollees is critical in aiding them to make informed decisions when selecting a health plan and to sufficiently understand the managed care program to maximize the benefits and rights available to them. For example, without information presented in an easily understood way, an enrollee may choose a health plan that does not have their existing providers in the network, which may force the enrollee to change their providers. This is particularly challenging for enrollees with disabilities or receiving LTSS, because these individuals often receive services that assist with activities of daily living in their home. Disruption in services from their usual providers can cause numerous problems and may prevent them from living safely and effectively in their chosen setting.

We propose changes to the content and delivery methods for notices, handbooks, and provider directories to facilitate the dissemination of timely and complete information that potential enrollees and enrollees need. Current § 438.10 pertaining to information requirements do not reflect current technology advances that enable states and managed care plans to provide access to information more quickly, accurately, and less expensively. As more consumers understand and rely on electronic information, not revising this section and continuing to mandate that all information be provided by mailing paper would be unrealistic, unnecessarily costly, and not in the beneficiaries'or managed care plans'

best interest. Many states and managed care plans have been providing required information in both electronic and paper form for several years. The revisions will eliminate this duplication. Since the transition to electronic communication will be gradual and at varying rates, we expect the burden for providing the information required in § 438.10 to diminish over time. The proposed provisions in § 438.10 have an estimated first-year COI cost of a cumulative $0.9 million (detailed burden estimates can be found in the COI section of this proposed rule at section IV.D.7 for information standards). As required by section 2103(f)(3) of the Act, added by section 403 of CHIPRA, and consistent with the requirements of section 2101(a) to provide coverage in an effective and efficient manner, we also propose to apply the standards of § 438.10 to CHIP in § 457.1207. The total estimated first-year COI costs associated with implementing the information requirements in part 457 is a cumulative $0.7 million.

11. Quality Measurement and Improvement

There are several items that are driving the new burden associated with the proposed quality revisions. Given that some PAHPs may provide clinical services, such as dental or behavioral health services, we propose to apply the quality standards in part 438 subpart E to PAHPs. This will ensure that they are subject to the same approach to measuring and improving quality as are MCOs and PIHPs, which will allow for better oversight and accountability. Revisions proposed for the quality assessment and performance improvement (QAPI) program at § 438.330 reflect the expansion of managed care to LTSS. By specifically addressing LTSS within their QAPI program, MCOs, PIHPs, and PAHPs will have tools that can be used to provide accountability for the care provided to this vulnerable population. The proposed new EQR-related activity (that is, validation of network adequacy) and state review and approval of MCOs, PIHPs, and PAHPs will also support state oversight of managed care plans, and help to ensure that consumers have access to high-quality plans. Similarly, state-based quality rating systems for MCOs, PIHPs, and PAHPs will assist consumers in identifying the plan that best meets their needs. The total estimated first-year COI costs associated with the modifications to the managed care quality components of the regulations is a cumulative $27.2 million (detailed burden estimates can be found in the COI section of this proposed rule at section IV.D.21 through IV.D.30 for quality framework).

States contracting with MCOs or PIHPs currently maintain a written strategy for assessing and improving the quality of managed care services offered by all MCOs and PIHPs. Regardless of delivery system, it is important to have a strategy for measuring performance to understand what is working and what needs to be improved. Because of this, we propose adding a new subpart I to part 431 which would extend the comprehensive quality strategy to all state Medicaid programs. States that contract with MCOs, PIHPs, or PAHPs would have to address managed care-specific elements described in § 438.340 within the comprehensive quality strategy. The proposed provisions in part 431 subpart I have an estimated first-year COI cost of a cumulative $0.1 million, with the creation and periodic evaluation and revision of the comprehensive quality strategy accounting for the complete cost. As required by section 2101(f)(3) of the Act, added by section 403 of CHIPRA, and consistent with the requirements of section 2101(a) to provide coverage in an effective and efficient manner, we also propose to apply the quality standards of 438 subpart E and 431 subpart I to CHIP in § 457.760, § 457.1240, and § 457.1250. The total estimated first-year COI costs associated with implementing the quality standards in part 457 is a cumulative $3.3 million.

The proposed regulation makes a number of changes related to Medicaid quality of care, primarily for Medicaid managed care programs, including requirements for comprehensive quality strategies, quality assessment and performance improvement, quality rating systems, state review and approval of performance of managed care plans by states, and external quality reviews. While these changes may lead to improvements in the quality of care delivered by states and Medicaid managed care plans, it is difficult to determine whether or not these changes would have any financial impacts on Medicaid expenditures. We would expect some activities would be unlikely to have a financial impact (such as state review and approval requirements), while other activities may lead to some small increases or decreases in expenditures. For example, some activities may require managed care plans to increase expenditures to improve the quality of care and meet certain quality standards associated with some of the proposed changes in the regulation, while other activities may improve the quality of care and lead to a net decrease in benefit expenditures. We believe that it is not possible to estimate the potential financial impacts of these proposed changes and believe that any impacts on net Medicaid expenditures would be negligible. We invite comment on possible ways to quantify the costs and/or benefits associated with these proposed provisions.

12. Network Adequacy

We propose a new § 438.68, to establish minimum standards in the area of network adequacy. This proposed section aims to maintain state flexibility while modernizing the current regulatory framework to reflect the maturity and prevalence of Medicaid managed care delivery systems, promote processes for ensuring access to care, and align, where feasible, with other private and public health care coverage programs. Therefore, we propose to set standards to ensure ongoing state assessment and certification of MCO, PIHP, and PAHP networks, set threshold standards for the establishment of network adequacy measures for a specified set of providers, establish criteria for developing network adequacy standards for MLTSS programs, and ensure the transparency of network adequacy standards. As many states currently have some network standards in place, we estimate only a small administrative burden to states to implement these provisions. In general, we would expect strengthening network adequacy standards could increase expenditures, as some plans would likely need to add more providers to in their networks and, in doing so, may need to increase provider reimbursement rates. In addition, adding more providers to plan networks could potentially lead to more use of health care services among the providers added, whether primary care physicians, specialists, or other providers. However, the proposed changes in the regulation are limited and only set requirements about setting and reporting network adequacy standards. The proposed regulation does not establish network adequacy standards. Thus, while a state may need to adapt its network adequacy standards to include criteria specified in the proposed regulation or to provide additional reports and information about those standards, we do not assume that these changes would likely lead to significant changes to the standards currently in place in states. Therefore, we believe that these proposed changes are likely to have no financial impact on future Medicaid

expenditures. To the extent that these proposed changes do lead to some states changing their current network adequacy standards, it is possible that future expenditures would increase if plans increase provider reimbursement rates to attract new providers to their networks or if greater access to care leads to more utilization of health care services. We invite comment on possible ways to quantify the costs and/or benefits associated with these proposed provisions.

13. Implementing Statutory Provisions

This guiding principle seeks to implement the statutory provisions impacting Medicaid and CHIP managed care that have passed since the Balanced Budget Act of 1997 (BBA). This principle covers the regulatory topics of incorporating provisions for encounter data and health information systems requirements established in the Affordable Care Act and requirements for contracts involving Indians established in the American Recovery and Reinvestment Act (ARRA). The total estimated first-year COI costs associated to the provisions under this principle account for a cumulative $0.1 million (provisions in §§ 438.14, 438.242, and 438.818) (detailed COI burden estimates can be found in the COI section of this proposed rule at sections IV.D.8 and IV.D.20 for encounter data and health information systems and IV.D.8 for contracts involving Indians). No additional quantifiable benefits or costs were identified for these provisions.

14. Other Provisions

Changes proposed in Subpart F of part 438 that include references to part 431 require minor changes to § 431.220 and § 431.244. Without these changes, the sections would be inconsistent with the changes proposed in part 438. There is no burden associated with this change as it is a technical correction and any related burden is included in § 438.408(f).

In § 433.138, technical corrections are being proposed to remove a soon-to-be obsolete reference to ''ICD–9'' and replace it with text that does not alter the meaning nor need to be updated as newer versions of the International Classification of Diseases are published in the future. There is no burden associated with this change as states are not mandated to make any changes to their policies or procedures as a result of this revised text.

C. Anticipated Effects

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that some PAHPs, PCCMs, and PCCM entities are likely to be small entities as that term is used in the RFA. For purposes of the RFA, we estimate that most MCOs and PIHPs are not small entities as that term is used in the RFA. For purposes of the RFA and according to the Small Business Administration (SBA) and the Table of Small Business Size Standards, small entities include small businesses in the health care sector that are direct health and medical insurance carriers with average annual receipts of less than $38.5 million and offices of physicians or health practitioners with average annual receipts of less than $11 million. For purposes of the RFA, individuals and state governments are not included in the definition of a small entity.

As of 2012, there are 331 MCOs, 176 PIHPs, 41 PAHPs, 20 NEMT PAHPs, 25 PCCMs, and 9 PCCM entities participating in the Medicaid managed care program. We estimate that there are an additional 66 entities that serve only CHIPs, including approximately 59 MCOs and PIHPs, 3 PAHPs, and 4 PCCMs. We believe that only a few of these entities qualify as small entities. Specifically, we believe that 10 to 20 PAHPs, 8 to 15 PCCMs, and 2 to 5 PCCM entities are likely to be small entities. We believe that the remaining MCOs and PIHPs have average annual receipts from Medicaid and CHIP contracts and other business interests in excess of $38.5 million. In analyzing the scope of the impact of these regulations on small entities, we examined the United States Census Bureau's Statistics of U.S. Businesses for 2010. According to the 2010 data, there are 4,414 direct health and medical insurance carriers with less than 20 employees and 158,607 offices of physicians or health practitioners with less than 20 employees. For purposes of the RFA, we believe that we are impacting less than 1 percent of the small entities that we have identified.

The primary impact on small entities will be through the standards proposed to be placed on PAHPs, PCCMs, and PCCM entities through the following requirements: (1) Adding PCCMs and PCCM entities, where appropriate, to the information standards in § 438.10 and § 457.1207 regarding enrollee handbooks, provider directories, and formularies; (2) adding PAHPs, PCCMs, and PCCM entities in § 438.62 to implement their own transition of care policies and PAHPs in § 438.208 to perform initial assessments and care coordination activities and applying these standards to CHIP in §§ 457.1216 and 457.1230(c); (3) adding PAHPs in § 438.242 to collect data on enrollee and provider characteristics and on services furnished to enrollees through an encounter data system or other such methods and applying these standards to CHIP in § 457.1230(d); (4) adding PCCM entities to the quality assessment and performance improvement program standards in § 438.330 and applying these standards to CHIP in § 457.1240; (5) adding PAHPs in § 438.350 to the list of affected entities regarding the EQR process and applying these standards to CHIP in § 457.1250; and (6) adding PAHPs to the types of entities subject to the standards of subpart F to establish a grievances and appeals system and process and applying these standards to CHIP in § 457.1260. We do not believe that the remaining impacts or burdens of the provisions of this proposed rule are great on the small entities that we have identified.

For purposes of the RFA, all cost estimates were derived from the Collection of Information calculations in section IV of this proposed rule. The estimated costs associated with the impacts on small entities listed above are primarily attributable to the transition of care policies for PAHPs, PCCMs, and PCCM entities, initial assessments and care coordination activities for PAHPs, and the establishment of a grievances and appeals system and process for PAHPs. The transition of care policies, initial assessments, and care coordination activities for PAHPs account for approximately $2.4 million of the cumulative $4.5 million annual impact on the 41 PAHPs (detailed burden estimates can be found in the COI section of this proposed rule at sections IV.D.10 and IV.D.17 for coordination/continuity of care). The establishment of a grievances and appeals system and process accounts for approximately $1.1 million of the cumulative $4.5 million annual impact on the 41 PAHPs (detailed burden estimates can be found in the COI section of this proposed rule at sections IV.D.31 through IV.D.35 for grievances and appeals). The total estimated annual burden per PAHP is less than $0.1 million, or less than 1 percent of the $38.5 million threshold. The transition of care policies for PCCMs and PCCM entities account for approximately $0.4 million of the cumulative $0.6 million annual impact on the 34 PCCMs and PCCM entities (detailed burden estimates can be found in the COI section of this proposed rule at sections IV.D.10 and IV.D.17 for coordination/continuity of care). The total estimated annual burden per

PCCM or PCCM entity is less than $0.1 million, or less than 1 percent of the $11 million threshold.

These small entities must meet certain standards as identified in the provisions of this proposed rule; however, we believe these are consistent with the nature of their business in contracting with state governments for the provision of services to Medicaid and CHIP managed care enrollees. Therefore, based on the estimates in the COI (section IV of this proposed rule), we have determined, and the Secretary certifies, that this proposed rule will not have a significant economic impact on a substantial number of small entities. We invite comment on our proposed analysis of the impact on small entities and on possible alternatives to provisions of the proposed rule that would reduce burden on small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds.

We do not anticipate that the provisions in this proposed rule will have a substantial economic impact on most hospitals, including small rural hospitals. Provisions include some proposed new standards for State governments, MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities but no direct requirements on individual hospitals. The impact on individual hospitals will vary according to each hospital's current and future contractual relationships with MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities, but any additional burden on small rural hospitals should be negligible. We invite comment on our proposed analysis of the impact on small rural hospitals regarding the provisions of this proposed rule.

We have determined that we are not preparing analysis for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals in comparison to total revenues of these entities.

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 2015, that is approximately $144 million. This proposed rule does not contain any federal mandate costs resulting from (A) imposing enforceable duties on state, local, or tribal governments, or on the private sector, or (B) increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs. We have determined that this proposed rule does not impose any mandates on state, local, or tribal governments, or the private sector that will result in an annual expenditure of $144 million or more.

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. We believe this proposed regulation gives states appropriate flexibility regarding managed care standards (for example, setting network adequacy standards, setting credentialing standards, EQR activities), while also aligning Medicaid and CHIP managed care standards with those for plans in the Marketplace and MA to better streamline the beneficiary experience and to reduce administrative and operational burdens on states and health plans across publicly-funded programs and the commercial market. We have determined that this proposed rule would not significantly affect states' rights, roles, and responsibilities.

1. Effects on Other Providers

The providers directly affected by the provisions of this rule are the MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities under contract to a state Medicaid or CHIP agency. As detailed in the sections above, the effect of the proposed rule varies by entity type and amount of burden. Setting actuarially sound rates and MLR are the areas with the largest impact on the managed care plans. We believe that many of the proposed rate setting provisions are unlikely to have a direct effect on the actual capitation rates or future Medicaid expenditures. To the extent that these new standards or requirements do have an effect on capitation rates or Medicaid expenditures, we believe that generally it is likely that this could lead to increases in some cases and decreases in other cases in the capitation payment rates and Medicaid expenditures. The sum of the estimated financial impacts of these changes could increase expenditures as much as $3.6 billion from 2016 to 2020 and could decrease expenditures as much as $11.0 billion from 2016 to 2020.

The regulation proposes new requirements that would require the states to calculate and report the medical loss ratios (MLRs) for Medicaid MCOs, PIHPs, and PAHPs in § 438.4 and § 438.5, and to add new § 438.8 and § 438.74. These changes, however, do not require that states assess any financial penalties on MCOs, PIHPs, and PAHPs that do not meet a minimum MLR. The net effect of these changes is estimated to range from zero impact to a decrease in MCO, PIHP, and PAHP payments of about 0.2 to 0.3 percent. Between 2018 and 2020, a 0.3-percent decrease in MCO, PIHP, and PAHP expenditures is projected to be a reduction of $1.6 billion in federal expenditures and of $0.9 billion in state expenditures.

Many other proposed changes in this rule will have small COI costs for MCOs, PIHPs, and PAHPs; however, they are negligible. All COI costs are described in section IV of this proposed rule.

2. Effects on the Medicare and Medicaid Programs

This rule has may have some positive effect on Medicare, but that effect is not quantifiable. Sections 438.62 and 438.208 propose enhanced care planning, transition, and coordination activities. Many of these activities will affect dually eligible enrollees. If, as expected, those efforts generate savings from more efficient and appropriate use of services, then Medicare as the primary payer may recognize some benefit.

The provisions of proposed part 431 subpart I will apply to Medicaid programs in all states and territories. The total estimated first-year COI cost for states is a cumulative $0.1 million, with 50 percent eligible for federal matching funds. This rule will help states to measure and improve the quality of care provided to all beneficiaries in the state, regardless of delivery system.

The provisions of proposed part 438 will apply to all states using a managed care delivery system for the Medicaid program. Federal matching rates are discussed more fully in section V.B, Overall Impact. This rule will help states fulfill the goals and mission of the Medicaid program through better oversight and accountability of their programs and will enable them to detect deficiencies and implement corrective action more quickly and consistently.

D. Alternatives Considered

One alternative considered was leaving part 438 as it is today. While it has been the guiding regulation for Medicaid managed care since its finalization in 2002, many questions and issues have arisen in the intervening 13 years due to the current version's lack of clarity or detail in some areas. The proposed revisions to the topics of rate setting and enrollment are good examples of this. With no guidance in these areas, states have created various standards, leading to inconsistency and, in some cases, less than optimal program performance. Additionally, many issues have arisen from the evolution of managed care in the last twelve years that have rendered parts of parts 438 nearly obsolete. For example, the existing version gives little acknowledgement to the use of electronic means of communication and no recognition to the recently created health care coverage options offered through the federal and state marketplaces. This creates gaps that leave states and managed care plans with unclear, non-existent, or confusing guidance and standards for program operation. We believe that with consistent standards and clearly defined flexibilities for states, programs can develop in ways that not only transform the healthcare delivery system and fulfill the mission of the Medicaid program, but can improve the health and wellness of Medicaid enrollees. For these reasons, we believe that leaving part 438 as it is now is not a viable option.

Another option was to align completely with standards applicable to plans in Medicare and/or the Marketplace. Given the high rate of cross program participation among the managed care plans in some states, we believe it is important to allow managed care plans to take advantage of operational efficiencies by aligning part 438 with Medicare and the private insurance market wherever possible by creating and implementing uniform policies and procedures. Alignment also adds consistency and ease of understanding for enrollees as they move between healthcare coverage programs as their life circumstances change. For each regulatory area where a comparable Medicare or Marketplace practice or policy existed, staff evaluated the information against existing Medicaid regulations. When differences were identified, they were evaluated to determine the benefits and drawbacks to adopting and the degree of impact the change would have on the Medicaid population, which is often significantly different from Medicare and the Marketplace populations. Additionally, as Medicaid is a federal-state partnership, we wanted to preserve the flexibility historically provided to states in the design and administration of their programs. As such, complete alignment was only an option in some provisions, while partial alignment was selected in others to recognize and accommodate the unique aspects of the Medicaid program.

Regarding quality measurement and improvement (part 438 subpart E) and comprehensive quality strategies (part 431 subpart I), two alternatives were considered: (1) Leaving the language as it exists today, and (2) revising the regulatory text for only states that contract with MCOs, PIHPs, and PAHPs. While our regulatory language has remained unchanged since 2002, there have been significant improvements regarding quality measurement and improvement for Medicaid. Under the authority of CHIPRA and the Affordable Care Act, we have developed and issued a set of performance measures to assess the quality of care received by adults and children in the Medicaid and CHIP programs. The National Quality Strategy and CMS Quality Strategy now offer national guidance regarding how we move forward as a nation to offer better health care, improved affordability, and support healthy people and healthy communities. At a state level, Medicaid managed care programs have undergone shifts both in terms of populations and benefits since 2002. Given these changes, we believe that is it necessary and appropriate to revise our regulatory language to address needs of the Medicaid programs both today and into the future. While the role of managed care in both Medicaid has grown since 2002, we cannot forget that many individuals still receive care through a FFS delivery model, and that certain services are still provided FFS to individuals otherwise enrolled in managed care programs. We believe that, regardless of delivery system, it is important for states to measure performance to develop a plan to strengthen and improve the quality of care. It is also important that managed care quality regulations support the programs as they exist today and into the future. Therefore, we determined that the most appropriate course of action would be to revise the Medicaid and CHIP managed care quality regulations, and to have states establish a comprehensive quality strategy for all delivery systems within their Medicaid programs.

For CHIP, we considered two alternatives: (1) Not regulating; or (2) adopting additional Medicaid requirements. CHIPRA applied several of the Medicaid managed care standards to CHIP. In response, we released two SHOs conveying those requirements to states, but have not provided additional guidance. As a result, states do not have clear understanding of the expectations of the federal requirements for CHIP managed care, and CMS does not have needed information about state oversight of managed care plans. Therefore, we determined that regulations were appropriate. When deciding whether to adopt all of the Medicaid regulations, or only the subset proposed in this regulation, we have worked to balance the need for information about state oversight of CHIP managed care plans against the administrative burden of complying with the proposed regulations. To that end, we propose to only apply the rules that are most important for aligning CHIP managed care with Marketplace and Medicaid managed care rules. The scope of the CHIP proposed regulations is narrower than the proposed revisions and amendments to the Medicaid managed care regulations.

E. Accounting Statement and Table

The estimates that appear in the Transfers section of Table 15 combine both cost savings and transfers between members of society. To the extent that the proposed rule changes provision of medical care, the impacts represent cost savings. Otherwise, the rule's impacts represent transfers to the federal and state governments from MCOs, PIHPs and PAHPs.

TABLE 15—ECONOMIC DATA: COSTS AND BENEFITS STATEMENT

				Units			
Category	Primary estimate	Low estimate	High estimate	Year dollars	Discount rate	Period covered	Notes
Benefits							
Non-Quantified	Improved health outcomes; reduced unnecessary services; improved beneficiary experience; improved access; and improved program transparency which facilitates better decision making.						
Costs							
Annualized Monetized $ millions/year.	112.8 112.7	....	....	2013 2013	7% 3%	2016–2020 2016–2020	
Non-Quantified	Costs of activities (other than information collection as defined in the Paperwork Reduction Act) that would be necessary for generating benefits listed above.						
Transfers							
Federal Annualized Monetized $ millions/year.	.....	−390.4 −395.8	1623.9 1655.6	2016 2016	7% 3%	2016–2020 2016–2020	
From/To	From: MCOs, PIHPS & PAHPs		To: Federal Government				
Other Annualized Monetized $ millions/year.	.....	−310.3 −315.8	985.8 1005.2	2016 2016	7% 3%	2016–2020 2016–2020	
From/To	From: MCOs, PIHPS & PAHPs		To: State Governments				

List of Subjects

42 CFR Part 431

Grant programs-health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 433

Administrative practice and procedure, Child support, Claims, Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 438

Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 440

Grant programs-health, Medicaid.

42 CFR Part 457

Administrative practice and procedure, Grant programs-health, Health insurance, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Electronic health records, Health facilities, Health professions, Health maintenance organizations (HMO), Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

■ 1. The authority citation for part 431 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act, (42 U.S.C. 1302).

■ 2. Section 431.200 is amended by revising paragraph (b) to read as follows:

§ 431.200 Basis and Scope.

* * * * *

(b) Prescribes procedures for an opportunity for a hearing if the State agency or non-emergency transportation PAHP (as defined in § 438.9(a) of this chapter) takes action, as stated in this subpart, to suspend, terminate, or reduce services, or an MCO, PIHP or PAHP takes action under subpart F of part 438 of this chapter; and

* * * * *

■ 3. Section 431.220 is amended by revising paragraphs (a)(5) and (a)(6) to read as follows:

§ 431.220 When a hearing is required.

(a) * * *

(5) Any MCO, PIHP, or PAHP enrollee who is entitled to a hearing under subpart F of part 438 of this chapter.

(6) Any enrollee in a Non-Emergency Medical Transportation PAHP (as that term is defined in § 438.9 of this chapter) who has an action as stated in this subpart.

* * * * *

■ 4. Section 431.244 is amended by—

■ a. Revising paragraphs (f)(1) and (f)(2) introductory text.

■ b. Removing paragraph (f)(3).

The revisions read as follows:

§ 431.244 Hearing decisions.

* * * * *

(f) * * *

(1) Ordinarily, within 90 days from the date the enrollee filed an MCO, PIHP, or PAHP appeal, not including the number of days the enrollee took to subsequently file for a State fair hearing.

(2) As expeditiously as the enrollee's health condition requires, but no later than 3 working days after the agency receives, from the MCO, PIHP, or PAHP, the case file and information for any appeal of a denial of a service that, as indicated by the MCO,PIHP, or PAHP—

* * * * *

■ 5. Subpart I is added to part 431 to read as follows:

Sec.

Subpart I—General Provisions

Subpart I—General Provisions

§ 431.500 Basis and scope.

(a) *Statutory basis.* This part is based on sections 1932(c), 1902(a)(4), 1902(a)(6), 1902(a)(19), and 1902(a)(22) of the Act.

(b) *Scope.* This part sets forth specifications for a comprehensive quality strategy that all States must implement to ensure the delivery of quality health care to all Medicaid beneficiaries.

§ 431.502 State comprehensive quality strategy.

(a) *General rule.* Each State must draft and implement a written, comprehensive quality strategy for assessing and improving the quality of health care and services furnished to all Medicaid beneficiaries.

(b) *Elements of the State comprehensive quality strategy.* At a minimum, the State's comprehensive quality strategy must include the following:

(1) The State's goals and objectives for continuous quality improvement, which must be measurable and take into consideration the health status of all populations served by the Medicaid program.

(2) Specific quality metrics and performance targets for measuring improvement and performance, including the identification of which quality metrics and performance outcomes the State will publish at least annually on the State's public Medicaid Web site.

§ 431.504 State comprehensive quality strategy development, evaluation, and revision.

In drafting and revising the comprehensive quality strategy, the State must:

(a) Obtain the input of the Medical Care Advisory Committee, required by § 431.12, beneficiaries, and other stakeholders (including Tribal consultation, as appropriate) in the development of the comprehensive quality strategy (and any revisions) and make the strategy available for public comment before submitting the strategy to CMS for review.

(b) Review and update the comprehensive quality strategy as needed, but no less than once every 3 years.

(1) This review must include an evaluation of the effectiveness of the comprehensive quality strategy conducted within the previous 3 years.

(2) The State must make the results and findings of the effectiveness evaluation of the comprehensive quality strategy available on the State's public Medicaid Web site.

(c) Submit to CMS the following:

(1) A copy of the initial strategy for CMS comment and feedback before adopting it in final.

(2) A copy of the revised strategy whenever significant changes are made to the document, or whenever significant changes occur within the State's Medicaid program. The State must include its definition of ''significant changes'' within each revised comprehensive quality strategy.

(d) The State must make the final comprehensive quality strategy available on the State's public Medicaid Web site.

§ 431.506 Applicability to Medicaid managed care programs.

Each State contracting with an MCO, PIHP, or PAHP as defined in § 438.2 of this chapter or with a PCCM entity as described in § 438.3(r) of this chapter must also address, within the comprehensive quality strategy, the requirements described in § 438.340 of this chapter.

PART 433—STATE FISCAL ADMINISTRATION

■ 6. The authority citation for part 433 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act, (42 U.S.C. 1302).

■ 7. Section 433.138 is amended by revising paragraph (e) to read as follows:

§ 433.138 Identifying liable third parties.

* * * * *

(e) *Diagnosis and trauma code edits.* Except as specified under paragraph (l) of this section, the agency must take action to identify those paid claims for Medicaid beneficiaries that contain diagnosis codes that are indicative of trauma, or injury, poisoning, and other consequences of external causes, for the purpose of determining the legal liability of third parties so that the agency may process claims under the third party liability payment procedures specified in § 433.139(b) through (f).

* * * * *

■ 8. Part 438 is revised to read as follows:

PART 438—MANAGED CARE

Sec.

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart A—General Provisions

§ 438.1 Basis and scope.

(a) *Statutory basis.* This part is based on the following statutory sections:

(1) Section 1902(a)(4) requires that States provide for methods of administration that the Secretary finds necessary for proper and efficient operation of the State plan. The application of the requirements of this part to PIHPs and PAHPs that do not meet the statutory definition of an MCO or a PCCM is under the authority in section 1902(a)(4).

(2) Section 1903(i)(25) prohibits payment to a State unless a State provides enrollee encounter data required by CMS.

(3) Section 1903(m) contains requirements that apply to comprehensive risk contracts.

(4) Section 1903(m)(2)(H) provides that an enrollee who loses Medicaid eligibility for not more than 2 months may be enrolled in the succeeding month in the same MCO or PCCM if that MCO or PCCM still has a contract with the State.

(5) Section 1905(t) contains requirements that apply to PCCMs.

(6) Section 1932—

(i) Provides that, with specified exceptions, a State may require Medicaid beneficiaries to enroll in MCOs or PCCMs.

(ii) Establishes the rules that MCOs, PCCMs, the State, and the contracts between the State and those entities must meet, including compliance with requirements in sections 1903(m) and 1905(t) of the Act that are implemented in this part.

(iii) Establishes protections for enrollees of MCOs and PCCMs.

(iv) Requires States to develop a quality assessment and performance improvement strategy.

(v) Specifies certain prohibitions aimed at the prevention of fraud and abuse.

(vi) Provides that a State may not enter into contracts with MCOs unless it has established intermediate sanctions that it may impose on an MCO that fails to comply with specified requirements.

(vii) Specifies rules for Indian enrollees, Indian health care providers, and Indian managed care entities.

(viii) Makes other minor changes in the Medicaid program.

(b) *Scope.* This part sets forth requirements, prohibitions, and procedures for the provision of Medicaid services through MCOs, PIHPs, PAHPs, PCCMs and PCCM entities. Requirements vary depending on the type of entity and on the authority under which the State contracts with the entity. Provisions that apply only when the contract is under a mandatory managed care program authorized by section 1932(a)(1)(A) of the Act are identified as such.

§ 438.2 Definitions.

As used in this part—

Actuary means an individual who meets the qualification standards established by the American Academy of Actuaries for an actuary and follows the practice standards established by the Actuarial Standards Board. In this part, Actuary refers to an individual who is acting on behalf of the State when used in reference to the development and certification of capitation rates.

Capitation payment means a payment the State makes periodically to a contractor on behalf of each beneficiary enrolled under a contract and based on the actuarially sound capitation rate for the provision of services under the State plan. The State makes the payment regardless of whether the particular beneficiary receives services during the period covered by the payment.

Choice counseling means the provision of information and services designed to assist beneficiaries in making enrollment decisions; it includes answering questions and identifying factors to consider when choosing among managed care health plans and primary care providers. Choice counseling does not include making recommendations for or against enrollment into a specific MCO, PIHP, or PAHP.

Comprehensive risk contract means a risk contract between the State and an MCO that covers comprehensive services, that is, inpatient hospital services and any of the following services, or any three or more of the following services:

(1) Outpatient hospital services.

(2) Rural health clinic services.

(3) Federally Qualified Health Center (FQHC) services.

(4) Other laboratory and X-ray services.

(5) Nursing facility (NF) services.

(6) Early and periodic screening, diagnostic, and treatment (EPSDT) services.

(7) Family planning services.

(8) Physician services.

(9) Home health services.

Enrollee means a Medicaid beneficiary who is currently enrolled in an MCO, PIHP, PAHP, PCCM, or PCCM entity in a given managed care program.

Enrollee encounter data means the information relating to the receipt of any item(s) or service(s) by an enrollee under a contract between a State and a MCO, PIHP, or PAHP that is subject to the requirements of §§ 438.242 and 438.818.

Federally qualified HMO means an HMO that CMS has determined is a qualified HMO under section 1310(d) of the PHS Act.

Health care professional means a physician or a provider, if coverage for the physician's or provider's services is under the managed care contract.

Health insuring organization (HIO) means a county operated entity, that in exchange for capitation payments, covers services for beneficiaries—

(1) Through payments to, or arrangements with, providers;

(2) Under a comprehensive risk contract with the State; and

(3) Meets the following criteria—

(i) First became operational prior to January 1, 1986; or

(ii) Is described in section 9517(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as amended by section 4734 of the Omnibus Budget Reconciliation Act of 1990 and section 205 of the Medicare Improvements for Patients and Providers Act of 2008).

Long-term services and supports (LTSS) means services and supports provided to beneficiaries of all ages who have functional limitations and/or chronic illnesses that have the primary purpose of supporting the ability of the beneficiary to live or work in the setting of their choice, which may include the individual's home, a provider-owned or controlled residential setting, a nursing facility, or other institutional setting.

Managed care organization (MCO) means an entity that has, or is seeking to qualify for, a comprehensive risk contract under this part, and that is—

(1) A Federally qualified HMO that meets the advance directives requirements of subpart I of part 489 of this chapter; or

(2) Any public or private entity that meets the advance directives requirements and is determined by the Secretary to also meet the following conditions:

(i) Makes the services it provides to its Medicaid enrollees as accessible (in terms of timeliness, amount, duration, and scope) as those services are to other Medicaid beneficiaries within the area served by the entity.

(ii) Meets the solvency standards of § 438.116.

Managed care program means a managed care delivery system operated by a State as authorized under section 1915(a), 1915(b), 1932(a), or 1115(a) of the Act.

Material adjustment means an adjustment that, using reasonable actuarial judgment, has a significant impact on the development of the capitation payment such that its omission or misstatement could impact a determination whether the development of the capitation rate is consistent with generally accepted actuarial principles and practices.

Network provider means any health care professional, group of health care professionals, or entity that receives Medicaid funding directly or indirectly to order, refer or render covered services as a result of the state's contract with an MCO, PIHP, or PAHP.

Nonrisk contract means a contract between the State and a PIHP or PAHP under which the contractor—

(1) Is not at financial risk for changes in utilization or for costs incurred under the contract that do not exceed the upper payment limits specified in § 447.362 of this chapter; and

(2) May be reimbursed by the State at the end of the contract period on the basis of the incurred costs, subject to the specified limits.

Potential enrollee means a Medicaid beneficiary who is subject to mandatory enrollment or may voluntarily elect to enroll in a given MCO, PIHP, PAHP, PCCM or PCCM entity, but is not yet an enrollee of a specific MCO, PIHP, PAHP, PCCM, or PCCM entity.

Prepaid ambulatory health plan (PAHP) means an entity that—

(1) Provides services to enrollees under contract with the State, and on the basis of capitation payments, or other payment arrangements that do not use State plan payment rates.

(2) Does not provide or arrange for, and is not otherwise responsible for the provision of any inpatient hospital or institutional services for its enrollees; and

(3) Does not have a comprehensive risk contract.

Prepaid inpatient health plan (PIHP) means an entity that—

(1) Provides services to enrollees under contract with the State, and on the basis of capitation payments, or other payment arrangements that do not use State plan payment rates.

(2) Provides, arranges for, or otherwise has responsibility for the provision of any inpatient hospital or institutional services for its enrollees; and

(3) Does not have a comprehensive risk contract.

Primary care means all health care services and laboratory services customarily furnished by or through a general practitioner, family physician, internal medicine physician, obstetrician/gynecologist, pediatrician, or other licensed practitioner as authorized by the State Medicaid program, to the extent the furnishing of those services is legally authorized in the State in which the practitioner furnishes them.

Primary care case management means a system under which:

(1) A PCCM contracts with the State to furnish case management services (which include the location, coordination and monitoring of primary health care services) to Medicaid beneficiaries; or

(2) A PCCM entity contracts with the State to provide a defined set of functions.

Primary care case management entity (PCCM entity) means an organization that provides any of the following functions, in addition to primary care case management services, for the State:

(1) Provision of intensive telephonic or face-to-face case management, including operation of a nurse triage advice line.

(2) Development of enrollee care plans.

(3) Execution of contracts with and/or oversight responsibilities for the activities of FFS providers in the FFS program.

(4) Provision of payments to FFS providers on behalf of the State.

(5) Provision of enrollee outreach and education activities.

(6) Operation of a customer service call center.

(7) Review of provider claims, utilization and practice patterns to conduct provider profiling and/or practice improvement.

(8) Implementation of quality improvement activities including administering enrollee satisfaction surveys or collecting data necessary for performance measurement of providers.

(9) Coordination with behavioral health systems/providers.

(10) Coordination with long-term services and supports systems/providers.

Primary care case manager (PCCM) means a physician, a physician group practice or, at State option, any of the following:

(1) A physician assistant.

(2) A nurse practitioner.

(3) A certified nurse-midwife.

Rate cells means a set of mutually exclusive categories of enrollees that is defined by one or more characteristics for the purpose of determining the

capitation rate and making a capitation payment; such characteristics may include age, gender, and region or geographic area. Each enrollee should be categorized in one of the rate cells and no enrollee should be categorized in more than one rate cell.

Risk contract means a contract between the State an MCO, PIHP or PAHP under which the contractor—

(1) Assumes risk for the cost of the services covered under the contract; and

(2) Incurs loss if the cost of furnishing the services exceeds the payments under the contract.

State means the Single State agency as specified in § 431.10 of this chapter.

§ 438.3 Standard contract requirements.

(a) *CMS review.* The CMS must review and approve all MCO, PIHP, and PAHP contracts, including those risk and nonrisk contracts that, on the basis of their value, are not subject to the prior approval requirement in § 438.806. Proposed final contracts must be submitted in the form and manner established by CMS. For States seeking approval of contracts prior to a specific effective date, proposed final contracts must be submitted to CMS for review no later than 90 days prior to the effective date of the contract.

(b) *Entities eligible for comprehensive risk contracts.* A State may enter into a comprehensive risk contract only with the following:

(1) An MCO.

(2) The entities identified in section 1903(m)(2)(B)(i), (ii), and (iii) of the Act.

(3) Community, Migrant, and Appalachian Health Centers identified in section 1903(m)(2)(G) of the Act. Unless they qualify for a total exemption under section 1903(m)(2)(B) of the Act, these entities are subject to the regulations governing MCOs under this part.

(4) An HIO that arranges for services and became operational before January 1986.

(5) An HIO described in section 9517(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as amended by section 4734(2) of the Omnibus Budget Reconciliation Act of 1990).

(c) *Payment.* The final capitation rate for each MCO, PIHP or PAHP must be specifically identified in the applicable contract submitted for CMS review and approval. The final capitation rates must be based only upon services covered under the State plan and additional services deemed by the State to be necessary to comply with the Mental Health Parity and Addiction Equity Act, and represent a payment amount that is adequate to allow the MCO, PIHP or PAHP to efficiently deliver covered services to Medicaid-eligible individuals in a manner compliant with contractual requirements.

(d) *Enrollment discrimination prohibited.* Contracts with MCOs, PIHPs, PAHPs, PCCMs and PCCM entities must provide as follows:

(1) The MCO, PIHP, PAHP, PCCM or PCCM entity accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by CMS), up to the limits set under the contract.

(2) Enrollment is voluntary, except in the case of mandatory enrollment programs that meet the conditions set forth in § 438.50(a).

(3) The MCO, PIHP, PAHP, PCCM or PCCM entity will not, on the basis of health status or need for health care services, discriminate against individuals eligible to enroll.

(4) The MCO, PIHP, PAHP, PCCM or PCCM entity will not discriminate against individuals eligible to enroll on the basis of race, color, national origin, sex, sexual orientation, gender identity, or disability and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin, sex, sexual orientation gender identity, or disability.

(e) *Services that may be covered by an MCO, PIHP, or PAHP.* An MCO, PIHP, or PAHP may cover, for enrollees, services that are in addition to those covered under the State plan as follows:

(1) Any services that the MCO, PIHP or PAHP voluntarily agree to provide, although the cost of these services cannot be included when determining the payment rates under paragraph (c) of this section.

(2) [Reserved]

(f) *Compliance with applicable laws and conflict of interest safeguards.* All contracts with MCOs, PIHPs, PAHPs, PCCMs and PCCM entities must:

(1) Comply with all applicable Federal and State laws and regulations including Title VI of the Civil Rights Act of 1964; Title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990 as amended; and section 1557 of the Patient Protection and Affordable Care Act.

(2) Comply with the conflict of interest safeguards described in § 438.58 and with the prohibitions described in section 1902(a)(4)(C) of the Act applicable to contracting officers, employees, or independent contractors.

(g) *Provider-preventable condition requirements.* All contracts with MCOs, PIHPs and PAHPs must comply with the requirements mandating provider identification of provider-preventable conditions as a condition of payment, as well as the prohibition against payment for provider-preventable conditions as set forth in § 434.6(a)(12) and § 447.26 of this chapter. MCOs, PIHPs, and PAHPs, must report all identified provider-preventable conditions in a form and frequency as specified by the State.

(h) *Inspection and audit of records and access to facilities.* All contracts must provide that the State, CMS, and the Office of the Inspector General may, at any time, inspect and audit any records or documents of the MCO, PIHP, PAHP, PCCM or PCCM entity or its subcontractors, and may, at any time, inspect the premises, physical facilities, and equipment where Medicaid-related activities or work is conducted.

(i) *Physician incentive plans.* (1) MCO, PIHP, and PAHP contracts must provide for compliance with the requirements set forth in §§ 422.208 and 422.210 of this chapter.

(2) In applying the provisions of §§ 422.208 and 422.210 of this chapter, references to ''MA organization,'' ''CMS,'' and ''Medicare beneficiaries'' must be read as references to ''MCO, PIHP, or PAHP,'' ''State,'' and ''Medicaid beneficiaries,'' respectively.

(j) *Advance directives.* (1) All MCO and PIHP contracts must provide for compliance with the requirements of § 422.128 of this chapter for maintaining written policies and procedures for advance directives.

(2) All PAHP contracts must provide for compliance with the requirements of § 422.128 of this chapter for maintaining written policies and procedures for advance directives if the PAHP includes, in its network, any of those providers listed in § 489.102(a) of this chapter.

(3) The MCO, PIHP, or PAHP subject to this requirement must provide adult enrollees with written information on advance directives policies, and include a description of applicable State law.

(4) The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the change.

(k) *Subcontracts.* All subcontracts must fulfill the requirements of this part for the service or activity delegated under the subcontract in accordance with § 438.230.

(l) *Choice of health professional.* The contract must allow each enrollee to choose his or her health professional to the extent possible and appropriate.

(m) *Audited financial reports.* The contract must require MCOs, PIHPs, and PAHPs to submit audited financial

reports on an annual basis. The audit must be conducted in accordance with generally accepted accounting principles and generally accepted auditing standards.

(n) [Reserved]

(o) *LTSS contract requirements.* Any contract with an MCO, PIHP or PAHP that includes LTSS as a covered benefit must require that any services covered under the contract that could be authorized through a waiver under section 1915(c) of the Act or a State plan amendment authorized through sections 1915(i) or 1915(k) of the Act be delivered in settings consistent with § 441.301(c)(4) of this chapter.

(p) *Special rules for certain HIOs.* Contracts with HIOs that began operating on or after January 1, 1986, and that the statute does not explicitly exempt from requirements in section 1903(m) of the Act, are subject to all the requirements of this part that apply to MCOs and contracts with MCOs. These HIOs may enter into comprehensive risk contracts only if they meet the criteria of paragraph (a) of this section.

(q) *Additional rules for contracts with PCCMs.* A PCCM contract must meet the following requirements:

(1) Provide for reasonable and adequate hours of operation, including 24-hour availability of information, referral, and treatment for emergency medical conditions.

(2) Restrict enrollment to beneficiaries who reside sufficiently near one of the PCCM's delivery sites to reach that site within a reasonable time using available and affordable modes of transportation.

(3) Provide for arrangements with, or referrals to, sufficient numbers of physicians and other practitioners to ensure that services under the contract can be furnished to enrollees promptly and without compromise to quality of care.

(4) Prohibit discrimination in enrollment, disenrollment, and re-enrollment, based on the beneficiary's health status or need for health care services.

(5) Provide that enrollees have the right to disenroll in accordance with § 438.56(c).

(r) *Additional rules for contracts with PCCM entities.* In addition to the requirements in paragraph (q) of this section, States must submit PCCM entity contracts to CMS for review and approval to ensure compliance with the provisions of this paragraph; § 438.10; and if the State's contract with the PCCM entity provides for shared savings, incentive payments or other financial reward for improved quality outcomes, § 438.330(b)(3), (c) and (e) and § 438.340, and § 438.350.

(s) *Requirements for MCOs, PIHPs, or PAHPs that provide covered outpatient drugs.* MCOs, PIHPs or PAHPs that are contractually obligated to provide coverage of covered outpatient drugs must include the following requirements:

(1) The MCO, PIHP or PAHP provides coverage of covered outpatient drugs as defined in section 1927(k)(2) of the Act, that meets the standards for such coverage imposed by section 1927 of the Act as if such standards applied directly to the MCO, PIHP, or PAHP.

(2) The MCO, PIHP, or PAHP reports drug utilization data that is necessary for States to bill manufacturers for rebates in accordance with section 1927(b)(1)(A) of the Act no later than 45 calendar days after the end of each quarterly rebate period. Such utilization information must include, at a minimum, information on the total number of units of each dosage form, strength, and package size by National Drug Code of each covered outpatient drug dispensed or covered by the MCO, PIHP, or PAHP.

(3) The MCO, PIHP or PAHP establishes procedures to exclude utilization data for covered outpatient drugs that are subject to discounts under the 340B drug pricing program from the reports required under paragraph (s)(2) of this section.

(4) The MCO, PIHP or PAHP must operate a drug utilization review program that complies with the requirements described in section 1927(g) of the Act, as if such requirement applied to the MCO, PIHP, or PAHP instead of the State.

(5) The MCO, PIHP or PAHP must provide a detailed description of its drug utilization review program activities to the State on an annual basis.

(6) The MCO, PIHP or PAHP must conduct a prior authorization program that complies with the requirements of section 1927(d)(5) of the Act, as if such requirements applied to the MCO, PIHP, or PAHP instead of the State.

(t) *Requirements for MCOs, PIHPs or PAHPs responsible for coordinating benefits for dually eligible individuals.* In a State that enters into a Coordination of Benefits Agreement with Medicare for FFS, an MCO, PIHP or PAHP contract that includes responsibility for coordination of benefits for individuals dually eligible for Medicaid and Medicare must require the MCO, PIHP or PAHP to enter into a Coordination of Benefits Agreement with Medicare and participate in the automated claims crossover process.

(u) *Payments to MCOs and PIHPs for enrollees that are a patient in an institution for mental disease.* The State may make a monthly capitation payment to an MCO or PIHP for an enrollee receiving inpatient treatment in an Institution for Mental Diseases, as defined in § 435.1010 of this chapter, so long as the facility is an inpatient hospital facility or a sub-acute facility providing crisis residential services, and length of stay in the IMD is for a short term stay of no more than 15 days during the period of the monthly capitation payment.

(v) *Recordkeeping requirements.* MCOs, PIHPs, and PAHPs must retain, and require subcontractors to retain, as applicable, the following information: enrollee grievance and appeal records in § 438.416, base data in § 438.5(c), MLR reports in § 438.8(k), and the data, information, and documentation specified in § 438.604, § 438.606, § 438.608, and § 438.610 for a period of no less than 6 years.

§ 438.4 Actuarial soundness.

(a) *Actuarially sound capitation rates defined.* Actuarially sound capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the MCO, PIHP, or PAHP for the time period and the population covered under the terms of the contract, and such capitation rates are developed in accordance with the requirements in paragraph (b) of this section.

(b) *CMS review and approval of actuarially sound capitation rates.* Capitation rates for MCOs, PIHPs, and PAHPs must be reviewed and approved by CMS as actuarially sound. To be approved by CMS, capitation rates must do all of the following:

(1) Have been developed in accordance with standards specified in § 438.5 and generally accepted actuarial principles and practices. Any proposed differences among capitation rates according to covered populations must not be based on the Federal financial participation percentage associated with the covered populations.

(2) Be appropriate for the populations to be covered and the services to be furnished under the contract.

(3) Be adequate to meet the requirements on MCOs, PIHPs, and PAHPs in §§ 438.206, 438.207, and 438.208.

(4) Be specific to payments for each rate cell under the contract. Payments from any rate cell must not cross-subsidize or be cross-subsidized by payments for any other rate cell.

(5) Be certified by an actuary as meeting the applicable requirements of this part, including § 438.3(c) and (e).

(6) Meet any applicable special contract provisions as specified in § 438.6.

(7) Be provided to CMS in a format and within a timeframe that meets requirements in § 438.7.

(8) Be developed in such a way that the MCO, PIHP, or PAHP would reasonably achieve a medical loss ratio standard, as calculated under § 438.8, of at least 85 percent for the rate year. The capitation rates may be developed in such a way that the MCO, PIHP, or PAHP would reasonably achieve a medical loss ratio standard greater than 85 percent, as calculated under § 438.8, as long as the capitation rates are adequate for necessary and reasonable administrative costs.

§ 438.5 Rate development standards.

(a) *Definitions.* As used in this section, the following terms have the indicated meanings:

Budget neutral means a standard for any risk sharing mechanism that recognizes both higher and lower expected costs among contracted MCOs, PIHPs, or PAHPs and does not create a net aggregate gain or loss across all payments.

Prospective risk adjustment means a methodology to account for anticipated variation in risk levels among contracted MCOs, PIHPs, or PAHPs that is derived from historical experience of the contracted MCOs, PIHPs, or PAHPs and applied to rates for the rating period for which the certification is submitted.

Retrospective risk adjustment means a methodology to account for variation in risk levels among contracted MCOs, PIHPs, or PAHPs that is derived from experience concurrent with the rating period of the contracted MCOs, PIHPs, or PAHPs subject to the adjustment and calculated at the expiration of the rating period.

Risk adjustment is a methodology to account for the health status of enrollees when predicting or explaining costs of services covered under the contract for defined populations or for evaluating retrospectively the experience of MCOs, PIHPs, or PAHPs contracted with the State.

(b) *Process and requirements for setting actuarially sound capitation rates.* In setting actuarially sound capitation rates, the State must follow the steps below in accordance with this section, or explain why they are not applicable:

(1) Consistent with paragraph (c) of this section, identify and develop the base utilization and price data.

(2) Consistent with paragraph (d) of this section, develop and apply trend factors, including cost and utilization, to base data that are developed from actual experience of the Medicaid population or a similar population in accordance with generally accepted actuarial practices and principles.

(3) Consistent with paragraph (e) of this section, develop the non-benefit component of the rate to account for reasonable expenses related to MCO, PIHP, or PAHP administration; taxes; licensing and regulatory fees; contribution to reserves; profit margin; cost of capital; or other operational costs associated with the MCO's, PIHP's, or PAHP's provision of State plan services to Medicaid enrollees.

(4) Consistent with paragraph (f) of this section, make appropriate and reasonable adjustments to account for changes to the base data, programmatic changes, non-benefit components, and any other adjustment necessary to establish actuarially sound rates.

(5) Take into account the MCO's, PIHP's, or PAHP's past medical loss ratio, as calculated and reported under § 438.8, in the development of the capitation rates, and consider the projected medical loss ratio in accordance with § 438.4(b)(7).

(6) Consistent with paragraph (g) of this section, select a risk adjustment methodology that uses generally accepted models and apply it in a budget neutral manner across all MCOs, PIHPs, or PAHPs in the program to calculate adjustments to the payments as necessary.

(c) *Base data.* (1) States must provide all the validated encounter data, FFS data (as appropriate), and audited financial reports (as defined in § 438.3(m)) that demonstrate experience for the populations to be served by the MCO, PIHP, or PAHP to the actuary developing the capitation rates for at least the three most recent and complete years prior to the rating period.

(2) States and their actuaries must use the most appropriate data, with the basis of the data being no older than from the three most recent and complete years prior to the rating period, for setting capitation rates. Such base data must be derived from the Medicaid population, or, if data on the Medicaid population is not available, derived from a similar population and adjusted to make the utilization and price data comparable to data from the Medicaid population. Data must be in accordance with actuarial standards for data quality and an explanation of why that specific data is used must be provided in the rate certification.

(3) *Exception.* (i) States that are unable to base their rates on data meeting the qualifications in paragraph (c)(2) of this section that the basis of the data be no older than from the three most recent and complete years prior to the rating period may request approval for an exception; the request must describe why an exception is necessary and describe the actions the state intends to take to come into compliance with those requirements.

(ii) States that request an exception from the base data standards established in this section must set forth a corrective action plan to come into compliance with the base data standards no later than 2 years from the rating period for which the deficiency was identified.

(d) *Trend.* Each trend must be reasonable and developed in accordance with generally accepted actuarial principles and practices. Trend must be developed from actual experience of the Medicaid population or from a similar population.

(e) *Non-benefit component of the rate.* The development of the non-benefit component of the rate must include appropriate and reasonable expenses related to MCO, PIHP, or PAHP administration, taxes, licensing and regulatory fees, contribution to reserves, profit margin, cost of capital, or other operational costs, consistent with § 438.3(c).

(f) *Adjustments.* Each adjustment must reasonably support the development of an accurate base data set for purposes of rate-setting, address appropriate programmatic changes, the health status of the enrolled population, or reflect non-benefit costs, and be developed in accordance with generally accepted actuarial principles and practices.

(g) *Risk adjustment.* Prospective or retrospective risk adjustment methodologies must be developed in a budget neutral manner consistent with generally accepted actuarial principles and practices.

§ 438.6 Special contract provisions related to payment.

(a) *Definitions.* As used in this part, the following terms have the indicated meanings:

Incentive arrangement means any payment mechanism under which a contractor may receive additional funds over and above the capitation rates it was paid for meeting targets specified in the contract.

Risk corridor means a risk sharing mechanism in which States and contractors may share in profits or losses under the contract outside of a predetermined threshold amount.

Withhold arrangement means any payment mechanism under which a portion of a capitation rate is withheld

from an MCO, PIHP, or PAHP and a portion of or all of the withheld amount will be paid to the MCO, PIHP, or PAHP for meeting targets specified in the contract.

(b) *Basic requirements.* (1) If used in the payment arrangement between the State and the MCO, PIHP, or PAHP, all applicable risk-sharing mechanisms, such as reinsurance, risk corridors, or stop-loss limits, must be described in the contract.

(2) Contracts with incentive arrangements may not provide for payment in excess of 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangement. For all incentive arrangements, the contract must provide that the arrangement is—

(i) For a fixed period of time.

(ii) Not to be renewed automatically.

(iii) Made available to both public and private contractors under the same terms of performance.

(iv) Not conditioned on intergovernmental transfer agreements.

(v) Necessary for the specified activities, targets, performance measures, and quality-based outcomes that support program initiatives.

(3) Contracts that provide for a withhold arrangement must ensure that the capitation payment minus any portion of the withhold that is not reasonably achievable is actuarially sound as determined by an actuary. The total amount of the withhold, achievable or not, must be reasonable and take into consideration the MCO's, PIHP's or PAHP's financial operating needs accounting for the size and characteristics of the populations covered under the contract, as well as the MCO's, PIHP's or PAHP's capital reserves as measured by the risk-based capital level, months of claims reserve, or other appropriate measure of reserves. The data, assumptions, and methodologies used to determine the portion of the withhold that is reasonably achievable must be submitted as part of the documentation required under § 438.7(b)(6). For all withhold arrangements, the contract must provide that the arrangement is—

(i) For a fixed period of time.

(ii) Not to be renewed automatically.

(iii) Made available to both public and private contractors under the same terms of performance.

(iv) Not conditioned on intergovernmental transfer agreements.

(v) Necessary for the specified activities, targets, performance measures, and quality-based outcomes that support program initiatives.

(4) If a State makes payments to providers for graduate medical education (GME) costs under an approved State plan, the State must adjust the actuarially sound capitation rates to account for the GME payments to be made on behalf of enrollees covered under the contract, not to exceed the aggregate amount that would have been paid under the approved State plan for FFS. States must first establish actuarially sound capitation rates prior to making adjustments for GME.

(c) *Delivery system and provider payment initiatives under MCO, PIHP, or PAHP contracts*—(1) *General rule.* Except as specified in paragraphs (c)(1)(i) through (iii) of this section, the State may not direct the MCO's, PIHP's or PAHP's expenditures under the contract.

(i) The State may require the MCO, PIHP or PAHP to implement value-based purchasing models for provider reimbursement, such as pay for performance arrangements, bundled payments, or other service payment models intended to recognize value or outcomes over volume of services.

(ii) The State may require MCOs, PIHPs, or PAHPs to participate in a multi-payer delivery system reform or performance improvement initiative.

(iii) The State may require the MCO, PIHP or PAHP to:

(A) Adopt a minimum fee schedule for all providers that provide a particular service under the contract; or

(B) Provide a uniform dollar or percentage increase for all providers that provide a particular service under the contract.

(2) *Process for approval.* (i) All contract arrangements that direct the MCO's, PIHP's or PAHP's expenditures must have written approval prior to implementation. To obtain written approval, a state must demonstrate, in writing, that the arrangement—

(A) Is based on the utilization and delivery of services;

(B) Directs expenditures equally, and using the same terms of performance, for all public and private providers providing the service under the contract;

(C) Expects to advance at least one of the goals and objectives in the comprehensive quality strategy in § 438.340;

(D) Has an evaluation plan that measures the degree to which the arrangement advances at least one of the goals and objectives in the comprehensive quality strategy in § 438.340;

(E) Does not condition provider participation on intergovernmental transfer agreements; and

(F) Not to be renewed automatically.

(ii) Any contract arrangements that direct the MCO's, PIHP's or PAHP's expenditures under paragraphs (c)(1)(i) or (c)(1)(ii) must also demonstrate, in writing, that the arrangement—

(A) Must make participation in the value-based purchasing initiative, delivery system reform or performance improvement initiative available, using the same terms of performance, to all public and private providers providing services under the contract related to the reform or improvement initiative;

(B) Must use a common set of performance measures across all of the payers and providers;

(C) May not set the amount or frequency of the expenditures; and

(D) Does not allow the State to recoup any unspent funds allocated for these arrangements from the MCO, PIHP, or PAHP.

§ 438.7 Rate certification submission.

(a) *CMS review and approval of the rate certification.* States must submit to CMS for review and approval, all MCO, PIHP, and PAHP rate certifications concurrent with the review and approval process for contracts as specified in § 438.3(a).

(b) *Documentation.* The rate certification must contain the following information:

(1) *Base data.* A description of the base data used in the rate setting process (including the base data requested by the actuary, the base data that was provided by the State, and an explanation of why any base data requested was not provided by the State) and of how the actuary determined which base data set was appropriate to use for the rating period.

(2) *Trend.* Each trend factor, including trend factors for changes in the utilization and price of services, applied to develop the capitation rates must be adequately described with enough detail so CMS or an actuary applying generally accepted actuarial principles and practices can understand and evaluate the following:

(i) The calculation of each trend used for the rating period and the reasonableness of the trend for the enrolled population.

(ii) Any meaningful difference in how a trend differs between the rate cells, service categories, or eligibility categories.

(3) *Non-benefit component of the rate.* The development of the non-benefit component of the rate must be adequately described with enough detail

so CMS or an actuary applying generally accepted actuarial principles and practices can identify each type of non-benefit expense that is included in the rate and evaluate the reasonableness of the cost assumptions underlying each expense.

(4) *Adjustments.* All adjustments used to develop the capitation rates must be adequately described with enough detail so that CMS, or an actuary applying generally accepted actuarial principles and practices, can understand and evaluate all of the following:

(i) How each material adjustment was developed and the reasonableness of the material adjustment for the enrolled population.

(ii) The cost impact of each material adjustment and the aggregate cost impact of non-material adjustments.

(iii) Where in the rate setting process the adjustment was applied.

(iv) A list of all non-material adjustments used in the rate development process.

(5) *Risk adjustment.* (i) All prospective risk adjustment methodologies must be adequately described with sufficient detail so that CMS or an actuary applying generally accepted actuarial principles and practices can understand and evaluate the following:

(A) The data, and any adjustments to that data, to be used to calculate the adjustment.

(B) The model, and any adjustments to that model, to be used to calculate the adjustment.

(C) The method for calculating the relative risk factors and the reasonableness and appropriateness of the method in measuring the risk factors of the respective populations.

(D) The magnitude of the adjustment on the capitation rate per MCO, PIHP, or PAHP.

(E) An assessment of the predictive value of the methodology compared to prior rating periods.

(F) Any concerns the actuary has with the risk adjustment process.

(ii) All retrospective risk adjustment methodologies must be adequately described with sufficient detail so that CMS or an actuary applying generally accepted actuarial principles and practices can understand and evaluate the following:

(A) The party calculating the risk adjustment.

(B) The data, and any adjustments to that data, to be used to calculate the adjustment.

(C) The model, and any adjustments to that model, to be used to calculate the adjustment.

(D) The timing and frequency of the application of the risk adjustment.

(E) Any concerns the actuary has with the risk adjustment process.

(6) *Special contract provisions.* A description of any of the special contract provisions related to payment in § 438.6 that are applied in the contract.

(c) *Rates paid under risk contracts.* The State, through its actuary, must certify the final rate paid under each risk contract and document the underlying data, assumptions and methodologies supporting that specific rate.

(1) The State may pay each MCO, PIHP or PAHP a capitation rate under the contract that is different than the capitation rate paid to another MCO, PIHP or PAHP, so long as the rate that is paid is independently developed and set in accordance with this part.

(2) If the State determines that a retroactive adjustment to the capitation rate is necessary, the retroactive adjustment must be supported by a rationale for the adjustment and the data, assumptions and methodologies used to develop the magnitude of the adjustment must be described in sufficient detail to allow CMS or an actuary to determine the reasonableness of the adjustment. These retroactive adjustments must be certified by an actuary in a revised rate certification and submitted as a contract amendment to be approved by CMS. All such adjustments are also subject to Federal timely filing requirements.

(d) *Provision of additional information.* The State must, upon CMS' request, provide additional information, whether part of the rate certification or additional supplemental materials, if CMS determines that information is pertinent to the approval of the certification under this part. The State must identify whether the information provided in addition to the rate certification is proffered by the State, the actuary, or another party.

§ 438.8 Medical loss ratio (MLR) standards.

(a) *Basic rule.* The State must ensure, through its contracts starting on or after January 1, 2017, that each MCO, PIHP, and PAHP calculate and report a MLR in accordance with this section. For multi-year contracts that do not start in 2017, the State must require the MCO, PIHP, or PAHP to calculate and report a MLR for the rating period that begins in 2017.

(b) *Definitions.* As used in this section, the following terms have the indicated meanings:

Credibility adjustment means an adjustment to the medical loss ratio for a partially credible MCO, PIHP, or PAHP to account for a difference between the actual and target medical loss ratios that may be due to random statistical variation.

Full credibility means a standard for which the experience of an MCO, PIHP, or PAHP is determined to be sufficient for the calculation of a medical loss ratio with a minimal chance that the difference between the actual and target medical loss ratio is not statistically significant. An MCO, PIHP, or PAHP that is assigned full credibility (or is fully credible) will not receive a credibility adjustment to its medical loss ratio.

Member months mean the number of months an enrollee or a group of enrollees is covered by an MCO, PIHP, or PAHP over a specified time period, such as a year.

MLR reporting year means a period of 12 months selected by the State, for which a MCO's, PIHP's, or PAHP's MLR experience is reported. This could be the contract year, calendar year, State fiscal year or Federal fiscal year, but must be consistent with the rating period used to develop the capitation rates paid to the MCO, PIHP, or PAHP.

No credibility means a standard for which the experience of an MCO, PIHP, or PAHP is determined to be insufficient for the calculation of a medical loss ratio. An MCO, PIHP, or PAHP that is assigned no credibility (or is non-credible) will not be measured against any medical loss ratio requirements.

Non-claims cost means those expenses for administrative services that are not: Incurred claims (as defined in paragraph (e)(1) of this section); expenditures on quality improving activities (as defined in paragraph (e)(2) of this section); or licensing and regulatory fees, or Federal and State taxes (as defined in paragraph (f)(2) of this section).

Partial credibility means a standard for which the experience of an MCO, PIHP, or PAHP is determined to be sufficient for the calculation of a medical loss ratio but with a non-negligible chance that the difference between the actual and target medical loss ratios is statistically significant. An MCO, PIHP, or PAHP that is assigned partial credibility (or is partially credible) will receive a credibility adjustment to its medical loss ratio.

(c) *MLR requirement.* If a State elects to mandate a minimum MLR for its MCOs, PIHPs, or PAHPs, that minimum MLR must be equal to or higher than 85 percent (the standard used for projecting actuarial soundness under § 438.4(b)) and the MLR must be calculated and reported for each MLR reporting year by

the MCO, PIHP, or PAHP consistent with this section.

(d) *Calculation of the MLR.* (1) The MLR experienced for each MCO, PIHP, or PAHP in a MLR reporting year is the ratio of the numerator (as defined in paragraph (e) of this section) to the denominator (as defined in paragraph (f) of this section). A MLR may be increased by a credibility adjustment, in accordance with paragraph (h) of this section.

(2) [Reserved]

(e) *Numerator.* (1) The numerator of an MCO's, PIHP's, or PAHP's MLR for a MLR reporting year is the sum of the MCO's, PIHP's, or PAHP's incurred claims (as defined in (e)(2) of this section); the MCO's, PIHP's, or PAHP's expenditures for activities that improve health care quality (as defined in paragraph (e)(3) of this section); and activities compliant with § 438.608(a)(1) through (5), (7), (8) and (b) (subject to paragraph (e)(4) of this section).

(2) *Incurred claims.* (i) Incurred claims must include the following:

(A) Direct claims that the MCO, PIHP, or PAHP paid to providers (including under capitated contracts with network providers) for services or supplies covered under the contract and medical services meeting the requirements of § 438.3(e) provided to enrollees.

(B) Unpaid claims reserves for the MLR reporting year, including claims reported in the process of adjustment.

(C) Withholds from payments made to network providers.

(D) Claims that are recoverable for anticipated coordination of benefits.

(E) Claims payments recoveries received as a result of subrogation.

(F) Incurred but not reported claims based on past experience, and modified to reflect current conditions such as changes in exposure, claim frequency or severity.

(G) Changes in other claims-related reserves.

(H) Reserves for contingent benefits and the medical claim portion of lawsuits.

(ii) Amounts that must be deducted from incurred claims include the following:

(A) Overpayment recoveries received from health care professionals.

(B) Prescription drug rebates received by the MCO, PIHP, or PAHP.

(C) State subsidies based on a stop-loss payment methodology.

(iii) Expenditures that must be included in incurred claims include the following:

(A) Payments made by an MCO, PIHP, or PAHP to mandated solvency funds.

(B) The amount of incentive and bonus payments made to network providers.

(C) The amount of claims payments recovered through fraud reduction efforts, not to exceed the amount of fraud reduction expenses. The amount of fraud reduction expenses shall not include activities specified in § 438.8(e)(4).

(iv) Amounts that must either be included in or deducted from incurred claims include the following:

(A) Respectively, net payments or receipts related to risk adjustment and risk corridor programs developed in accordance with § 438.5 or § 438.6.

(B) [Reserved]

(v) Amounts that must be excluded from incurred claims:

(A) Non-claims costs, as defined in paragraph (b) of this section, which include the following:

(*1*) Amounts paid to third party vendors for secondary network savings.

(*2*) Amounts paid to third party vendors for network development, administrative fees, claims processing, and utilization management.

(*3*) Amounts paid, including amounts paid to a health care professional, for professional or administrative services that do not represent compensation or reimbursement for State plan services or services meeting the definition in § 438.3(e) and provided to an enrollee.

(*4*) Fines and penalties assessed by regulatory authorities.

(B) Amounts paid to the State as remittance under paragraph (j) of this section.

(vi) Incurred claims paid by one MCO, PIHP, or PAHP that is later assumed by another entity must be reported by the assuming MCO, PIHP, or PAHP for the entire MLR reporting year and no incurred claims for that MLR reporting year may be reported by the ceding MCO, PIHP, or PAHP.

(3) *Activities that improve health care quality.* Activities that improve health care quality must be in one of the following categories:

(i) An MCO, PIHP, or PAHP activity that meets the requirements of 45 CFR 158.150(b) and is not excluded under 45 CFR 158.150(c).

(ii) An MCO, PIHP, or PAHP activity related to any EQRO activity as described in § 438.358(b) and (c).

(iii) Any MCO, PIHP, or PAHP expenditure that is related to Health Information Technology and meaningful use, meets the requirements placed on issuers found in 45 CFR 158.151, and is not considered incurred claims, as defined in paragraph (e)(2) of this section.

(4) *Activities compliant with § 438.608.* MCO, PIHP, or PAHP expenditures on activities related to the program integrity requirements in § 438.608(a)(1) through (5), (7), (8) and (b), limited to 0.5 percent of premium revenue. Expenditures under this paragraph shall not include expenses for fraud reduction efforts in § 438.8(e)(2)(iii)(C).

(f) *Denominator.* (1) For a MLR reporting year the denominator of the MLR must equal the adjusted premium revenue. The adjusted premium revenue is the MCO's, PIHP's, or PAHP's premium revenue (as defined in paragraph (f)(2) of this section) minus the MCO's, PIHP's, or PAHP's Federal and State taxes and licensing and regulatory fees (as defined in paragraph (f)(3) of this section) and is aggregated in accordance with paragraph (i) of this section.

(2) *Premium revenue.* Premium revenue includes the following for the MLR reporting year:

(i) State capitation payments, developed in accordance with § 438.4, to the MCO, PIHP, or PAHP for all enrollees under a risk contract approved under § 438.3(a).

(ii) State-developed one time payments, for specific life events of enrollees.

(iii) Other payments to the MCO, PIHP, or PAHP under the contract approved under § 438.6, such as incentive arrangement payments or withhold payments.

(iv) Unpaid cost-sharing amounts that the MCO, PIHP, or PAHP could have collected from enrollees under the contract, except those amounts the MCO, PIHP, or PAHP can show it made a reasonable, but unsuccessful, effort to collect.

(v) All changes to unearned premium reserves.

(3) *Federal and State taxes and licensing and regulatory fees.* Taxes, licensing and regulatory fees for the MLR reporting year include:

(i) Statutory assessments to defray the operating expenses of any State or Federal department.

(ii) Examination fees in lieu of premium taxes as specified by State law.

(iii) Federal taxes and assessments allocated to MCOs, PIHPs, and PAHPs, excluding Federal income taxes on investment income and capital gains and Federal employment taxes.

(iv) State taxes and assessments including:

(A) Any industry-wide (or subset) assessments (other than surcharges on specific claims) paid to the State directly.

(B) Guaranty fund assessments.

(C) Assessments of State industrial boards or other boards for operating expenses or for benefits to sick employed persons in connection with

disability benefit laws or similar taxes levied by States.

(D) State income, excise, and business taxes other than premium taxes and State employment and similar taxes and assessments.

(E) State premium taxes plus State taxes based on reserves, if in lieu of premium taxes.

(v) Payments made by an MCO, PIHP, or PAHP, which is otherwise exempt from Federal income taxes, for community benefit expenditures as defined in 45 CFR 158.162(c), limited to the highest of either:

(A) Three percent of earned premium; or

(B) The highest premium tax rate in the State for which the report is being submitted, multiplied by the MCO's, PIHP's, or PAHP's earned premium in the State.

(4) The total amount of the denominator for a MCO, PIHP, or PAHP which is later assumed by another entity must be reported by the assuming MCO, PIHP, or PAHP for the entire MLR reporting year and no amount under this paragraph for that year may be reported by the ceding MCO, PIHP, or PAHP.

(g) *Allocation of expense*—(1) *General requirements.* (i) Each expense must be included under only one type of expense, unless a portion of the expense fits under the definition of, or criteria for, one type of expense and the remainder fits into a different type of expense, in which case the expense must be pro-rated between types of expenses.

(ii) Expenditures that benefit multiple contracts or populations, or contracts other than those being reported, must be reported on a pro rata basis.

(2) *Methods used to allocate expenses.* (i) Allocation to each category must be based on a generally accepted accounting method that is expected to yield the most accurate results.

(ii) Shared expenses, including expenses under the terms of a management contract, must be apportioned pro rata to the contract incurring the expense.

(iii) Expenses that relate solely to the operation of a reporting entity, such as personnel costs associated with the adjusting and paying of claims, must be borne solely by the reporting entity and are not to be apportioned to the other entities.

(h) *Credibility adjustment.* (1) A MCO, PIHP, or PAHP may add a credibility adjustment to a calculated MLR if the MLR reporting year experience is partially credible. The credibility adjustment is added to the reported MLR calculation before calculating any remittances, if required by the State as described in paragraph (j) of this section.

(2) A MCO, PIHP, or PAHP may not add a credibility adjustment to a calculated MLR if the MLR reporting year experience is fully credible.

(3) If a MCO's, PIHP's, or PAHP's experience is non-credible, it is presumed to meet or exceed the MLR calculation standards in this section.

(4) On an annual basis, CMS will publish base credibility factors for MCOs, PIHPs, and PAHPs that are developed according to the following methodology:

(i) CMS will use the most recently available and complete managed care encounter data or FFS claims data, and enrollment data, reported by the states to CMS. This data may cover more than 1 year of experience.

(ii) CMS will calculate the credibility adjustment so that a MCO, PIHP, or PAHP receiving a capitation payment that is estimated to have a medical loss ratio of 85 percent would be expected to experience a loss ratio less than 85 percent 1 out of every 4 years, or 25 percent of the time.

(iii) The minimum number of member months necessary for a MCO's, PIHP's, or PAHP's medical loss ratio to be determined at least partially credible will be set so that the credibility adjustment would not exceed 10 percent for any partially credible MCO, PIHP, or PAHP. Any MCO, PIHP, or PAHP with enrollment less than this number of member months will be determined non-credible.

(iv) The minimum number of member months necessary for an MCO's, PIHP's, or PAHP's medical loss ratio to be determined fully credible will be set so that the minimum credibility adjustment for any partially credible MCO, PIHP, or PAHP would be greater than 1 percent. Any MCO, PIHP, or PAHP with enrollment greater than this number of member months will be determined fully credible.

(v) A MCO, PIHP, or PAHP with a number of enrollee member months between the levels established for non-credible and fully credible plans will be deemed partially credible, and CMS will develop adjustments, using linear interpolation, based on the number of enrollee member months.

(vi) CMS may adjust the number of enrollee member months necessary for a MCO's, PIHP's, or PAHP's experience to be non-credible, partially credible, or fully credible so that the standards are rounded for the purposes of administrative simplification. The number of member months will be rounded to 1,000 or a different degree of rounding as appropriate to ensure that the credibility thresholds are consistent with the objectives of this regulation.

(i) *Aggregation of data*—(1) *Aggregation by covered population.* MCOs, PIHPs, or PAHPs will aggregate data for all Medicaid eligibility groups covered under the contract with the State unless the State requires separate reporting and a separate MLR calculation for specific populations.

(2) [Reserved]

(j) *Remittance to the State if Specific MLR is not met.* If required by the State, a MCO, PIHP, or PAHP must provide a remittance for an MLR reporting year if the MLR for that MLR reporting year does not meet the minimum MLR standard of 85 percent or higher if set by the State as described in paragraph (c) of this section.

(k) *Reporting requirements.* (1) The State, through its contracts, must require each MCO, PIHP, or PAHP to submit a report to the State that includes at least the following information for each MLR reporting year:

(i) Total incurred claims.

(ii) Expenditures on quality improving activities.

(iii) Expenditures related to activities compliant with § 438.608(a)(1) through (5), (7), (8) and (b).

(iv) Non-claims costs.

(v) Premium revenue.

(vi) Taxes, licensing and regulatory fees.

(vii) Methodology for allocation of expenditures.

(viii) Any credibility adjustment applied.

(ix) The calculated MLR.

(x) Any remittance owed to the State, if applicable.

(xi) A reconciliation of the information reported in this paragraph with the audited financial report required under § 438.3(m).

(xii) A description of the aggregation method used under paragraph (i) of this section.

(xiii) The number of member months.

(2) A MCO, PIHP, or PAHP must submit the report required in paragraph (k)(1) of this section in a timeframe and manner determined by the State, which must be within 12 months of the end of the MLR reporting year.

(3) MCOs, PIHPs, or PAHPs must require any third party vendor supplying Medicaid services to its enrollees to provide all underlying data associated with MLR reporting to that MCO, PIHP, or PAHP within 180 days of the end of the MLR reporting year or within 30 days of being requested by the MCO, PIHP, or PAHP, whichever comes sooner, regardless of current contractual limitations, to calculate and validate the accuracy of MLR reporting.

(l) *Newer experience.* A State, in its discretion, may exclude a MCO, PIHP, or PAHP that is newly contracted with the State from the requirements in this section for the first year of the MCO's, PIHP's, or PAHP's operation. Such MCOs, PIHPs, or PAHPs must be required to comply with the requirements in this section during the next MLR reporting year in which the MCO, PIHP, or PAHP is in business with the State, even if the first year was not a full 12 months.

(m) *Recalculation of MLR.* In any instance where a State makes a retroactive change to the capitation payments for a MLR reporting year where the report has already been submitted to the State, the MCO, PIHP, or PAHP must re-calculate the MLR for all MLR reporting years affected by the change and submit a new report meeting the requirements in paragraph (k) of this section.

(n) *Attestation.* MCOs, PIHPs, and PAHPs must attest to the accuracy of the calculation of the MLR in accordance with requirements of this section when submitting the report required under paragraph (k) of this section.

§ 438.9 Provisions that apply to non-emergency medical transportation PAHPs.

(a) For purposes of this section, Non-Emergency Medical Transportation (NEMT) PAHP means an entity that provides only NEMT services to enrollees under contract with the State, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates.

(b) Unless listed in this paragraph, a requirement of this part does not apply to NEMT PAHPs, NEMT PAHP contracts, or States in connection with a NEMT PAHP. The following requirements and options apply to NEMT PAHPs, NEMT PAHP contracts, and States in connection with NEMT PAHPs, to the same extent that they apply to PAHPs, PAHP contracts, and States in connection with PAHPs.

(1) All contract provisions in § 438.3 except requirements for:

(i) Physician Incentive plans.

(ii) Advance directives.

(iii) LTSS requirements.

(iv) MHPAEA.

(2) The actuarial soundness requirements in § 438.4.

(3) The information requirements in § 438.10.

(4) The provision against provider discrimination in § 438.12.

(5) The State responsibility provisions in §§ 438.56, 438.58, 438.60, and 438.62(a).

(6) The provisions on enrollee rights and protections in subpart C of this part except for §§ 438.110 and 438.114.

(7) The PAHP standards in §§ 438.206(b)(1), 438.210, 438.214, 438.224, 438.230, and 438.242.

(8) An enrollee's right to a State fair hearing under subpart E of part 431 of this chapter.

(9) Prohibitions against affiliations with individuals debarred or excluded by Federal agencies in § 438.610.

§ 438.10 Information requirements.

(a) *Definitions.* As used in this section, the following terms have the indicated meanings:

Prevalent means a non-English language determined to be spoken by a significant number or percentage of potential enrollees and enrollees that are limited English proficient and consistent with standards used by the Office for Civil Rights in enforcing anti-discrimination provisions.

Readily accessible means electronic information and services which comply with modern accessibility standards such as Section 508 guidelines or guidelines that provide greater accessibility to individuals with disabilities.

(b) *Applicability.* The provisions of this section apply to all managed care programs which operate under any authority in the Act.

(c) *Basic rules.* (1) Each State, enrollment broker, MCO, PIHP, PAHP, PCCM, and PCCM entity must provide all required information in this section to enrollees and potential enrollees in a manner and format that may be easily understood and readily accessible by such enrollees and potential enrollees.

(2) The State must utilize its beneficiary support system required in § 438.71.

(3) The State must operate a Web site that provides the content specified in paragraphs (g) and (h) of this section, § 438.68(e), § 438.364(b)(2), and § 438.602(g), either directly or by linking to individual MCO, PIHP, PAHP or PCCM entity Web sites.

(4) For consistency in the information provided to enrollees, the State must develop and require each MCO, PIHP, PAHP and PCCM entity to use:

(i) Definitions for managed care terminology, including appeal, co-payment, durable medical equipment, emergency medical condition, emergency medical transportation, emergency room care, emergency services, excluded services, grievance, habilitation services, health insurance, home health care, hospice services, hospitalization, hospital outpatient care, medically necessary, network, non-participating provider, physician services, plan, preauthorization, participating provider, premium, prescription drug coverage, prescription drugs, primary care physician, primary care provider, provider, rehabilitation services, skilled nursing care, specialist, and urgent care; and

(ii) Model member handbooks and member notices.

(5) The State must ensure, through its contracts, that each MCO, PIHP, PAHP and PCCM entity provides the required information in this section to each enrollee.

(6) Enrollee information required in this section may not be provided electronically by the State, MCO, PIHP, PAHP, PCCM or PCCM entity unless all of the following are met:

(i) The format is readily accessible.

(ii) The information is placed in a location on the State, MCO, PIHP, PAHP, or PCCM entity Web site that is prominent and readily accessible.

(iii) The information is provided in an electronic form which can be electronically retained and printed.

(iv) The information is consistent with the content and language requirements of this section.

(v) The State, MCO, PIHP, PAHP, and PCCM entity informs the enrollee that the information is available in paper form without charge upon request and provides it upon request within 5 calendar days.

(7) Each MCO, PIHP, PAHP, and PCCM entity must have in place a mechanism to help enrollees and potential enrollees understand the requirements and benefits of the plan.

(d) *Language and format.* The State must:

(1) Establish a methodology for identifying the prevalent non-English languages spoken by enrollees and potential enrollees throughout the State, and in each MCO, PIHP, PAHP, or PCCM entity service area.

(2) Make available oral and written information in each prevalent non-English language. All written materials for potential enrollees must include taglines in each prevalent non-English language as well as large print explaining the availability of written translations or oral interpretation to understand the information provided and the toll-free telephone number of the entity providing choice counseling services as required by § 438.71(a). Large print means printed in a font size no smaller than 18 pt.

(3) Require each MCO, PIHP, PAHP, and PCCM entity to make its written materials, including, at a minimum, provider directories, member handbooks, appeal and grievance

notices and other notices that are critical to obtaining services, available in the prevalent non-English languages in its particular service area. Written materials must also be made available in alternative formats and auxiliary aids and services should be made available upon request of the potential enrollee or enrollee at no cost.

(i) All written materials for enrollees, including provider directories, member handbooks, appeal and grievance notices and other notices that are critical to obtaining services, must include taglines in each prevalent non-English language as well as large print explaining the availability of written translations or oral interpretation to understand the information provided and the toll-free and TTY/TDY telephone number of the MCO's, PIHP's, PAHP's or PCCM entity's member/customer service unit. Large print means printed in a font size no smaller than 18 pt.

(ii) [Reserved]

(4) Make interpretation services available to each potential enrollee and require each MCO, PIHP, PAHP, and PCCM entity to make those services available free of charge to each enrollee. This includes oral interpretation and the use of auxiliary aids such as TTY/TDY and American sign language. Oral interpretation requirements apply to all non-English languages, not just those that the State identifies as prevalent.

(5) Notify potential enrollees, and require each MCO, PIHP, PAHP, and PCCM entity to notify its enrollees—

(i) That oral interpretation is available for any language and written information is available in prevalent languages;

(ii) That auxiliary aids and services are available upon request and at no cost for enrollees with disabilities; and

(iii) How to access those services.

(6) Provide, and require MCOs, PIHPs, PAHPs, PCCMs or PCCM entities to provide, all written materials for potential enrollees and enrollees consistent with the following:

(i) Use easily understood language and format.

(ii) Use a font size no smaller than 12 point.

(iii) Be available in alternative formats and through the provision of auxiliary aids and services in an appropriate manner that takes into consideration the special needs of enrollees or potential enrollees with disabilities or limited English proficiency.

(iv) Include a large print tagline and information on how to request auxiliary aids and services, including the provision of the materials in alternative formats. Large print means printed in a font size no smaller than 18 pt.

(e) *Information for potential enrollees.* (1) The State or its contracted representative must provide the information specified in paragraph (e)(2) of this section to each potential enrollee, either in paper or electronic form as follows:

(i) At the time the potential enrollee first becomes eligible to enroll in a voluntary program, or is first required to enroll in a mandatory enrollment program.

(ii) Within a timeframe that enables the potential enrollee to use the information in choosing among available MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities.

(2) The information for potential enrollees must include at a minimum the following:

(i) Information about the potential enrollee's right to disenroll consistent with the requirements of § 438.56 and which explains clearly the process for exercising this disenrollment right, as well as the alternatives available to the potential enrollee based on their specific circumstance.

(ii) The basic features of managed care.

(iii) Which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in the program.

(iv) The service area covered by each MCO, PIHP, PAHP, PCCM, or PCCM entity.

(v) Covered benefits including

(A) Which benefits are provided by the MCO, PIHP, or PAHP; and

(B) Which, if any, benefits are provided directly by the State.

(C) For a counseling or referral service that the MCO, PIHP, or PAHP does not cover because of moral or religious objections, the State must provide information about where and how to obtain the service.

(vi) The provider directory information required in paragraph (h) of this section.

(vii) Any cost-sharing that will be imposed by the MCO, PIHP, PAHP, PCCM or PCCM entity consistent with those set forth in the State plan.

(viii) The requirements for each MCO, PIHP or PAHP to provide adequate access to covered services, including the network adequacy standards established in § 438.68.

(ix) MCO, PIHP, PAHP, PCCM and PCCM entity's responsibilities for coordination of enrollee care.

(x) To the extent available, quality and performance indicators for each MCO, PIHP, PAHP and PCCM entity, including enrollee satisfaction.

(f) *Information for all enrollees of MCOs, PIHPs, PAHPs, and PCCM entities: General requirements.* (1) The MCO, PIHP, PAHP and, when appropriate, the PCCM entity, must make a good faith effort to give written notice of termination of a contracted provider, within 15 calendar days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider.

(2) The State must notify all enrollees of their right to disenroll consistent with the requirements of § 438.56 at least annually. Such notification must clearly explain the process for exercising this disenrollment right, as well as the alternatives available to the enrollee based on their specific circumstance. For States that choose to restrict disenrollment for periods of 90 days or more, States must send the notice no less than 60 calendar days before the start of each enrollment period.

(3) The MCO, PIHP, PAHP and, when appropriate, the PCCM entity must make available, upon request, any physician incentive plans in place as set forth in § 438.3(i).

(g) *Information for enrollees of MCOs, PIHPs, PAHPs and PCCM entities—Enrollee handbook.* (1) Each MCO, PIHP, PAHP and PCCM entity must provide each enrollee an enrollee handbook, within a reasonable time after receiving notice of the beneficiary's enrollment, which serves a similar function as the summary of benefits and coverage described in 45 CFR 147.200(a).

(2) The content of the member handbook must include information that enables the enrollee to understand how to effectively use the managed care program. This information must include at a minimum:

(i) Benefits provided by the MCO, PIHP, PAHP or PCCM entity.

(ii) How and where to access any benefits provided by the State, including any cost sharing, and how transportation is provided.

(A) In the case of a counseling or referral service that the MCO, PIHP, PAHP, or PCCM entity does not cover because of moral or religious objections, the MCO, PIHP, PAHP, or PCCM entity must inform enrollees that the service is not covered.

(B) The MCO, PIHP, PAHP, or PCCM entity must inform enrollees how they can to obtain information from the State about how to access those services.

(iii) The amount, duration, and scope of benefits available under the contract in sufficient detail to ensure that

enrollees understand the benefits to which they are entitled.

(iv) Procedures for obtaining benefits, including any requirements for service authorizations and/or referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider.

(v) The extent to which, and how, after-hours and emergency coverage are provided, including:

(A) What constitutes an emergency medical condition and emergency services.

(B) The fact that prior authorization is not required for emergency services.

(C) The fact that, subject to the provisions of this section, the enrollee has a right to use any hospital or other setting for emergency care.

(vi) Any restrictions on the enrollee's freedom of choice among network providers.

(vii) The extent to which, and how, enrollees may obtain benefits, including family planning services and supplies, from out-of-network providers.

(viii) Cost sharing, if any is imposed under the State plan.

(ix) Enrollee rights and responsibilities, including the elements specified in § 438.100.

(x) The process of selecting and changing the enrollee's primary care provider.

(xi) Grievance, appeal, and fair hearing procedures and timeframes, consistent with subpart F of this part, in a State-developed or State-approved description. Such information must include:

(A) The right to file grievances and appeals.

(B) The requirements and timeframes for filing a grievance or appeal.

(C) The availability of assistance in the filing process.

(D) The right to request a State fair hearing after the MCO, PIHP or PAHP has made a determination on an enrollee's appeal which is adverse to the enrollee.

(E) The fact that, when requested by the enrollee benefits that the MCO, PIHP, or PAHP seeks to reduce or terminate will continue if the enrollee files an appeal or a request for State fair hearing within the timeframes specified for filing, the enrollee may, consistent with state policy, be required to pay the cost of services furnished while the appeal or State Fair Hearing is pending if the final decision is adverse to the enrollee.

(xii) How to exercise an advance directive, as set forth in § 438.3(j). For PAHPs, information must be provided only to the extent that the PAHP includes any of the providers described in § 489.102(a) of this chapter.

(xiii) How to access auxiliary aids and services, including additional information in in alternative formats or languages.

(xiv) The toll-free telephone number for member services medical management and any other unit providing services directly to enrollees.

(xv) Information on how to report suspected fraud or abuse;

(xvi) Any other content required by the State.

(3) Information required by this paragraph to be provided by a MCO, PIHP, PAHP or PCCM entity will be considered to be provided if the MCO, PIHP, PAHP or PCCM entity:

(i) Mails a printed copy of the information to the enrollee's mailing address;

(ii) Provides the information by email after obtaining the enrollee's agreement to receive the information by email;

(iii) Posts the information on the Web site of the MCO, PIHP, PAHP or PCCM entity and advises the enrollee in paper or electronic form that the information is available on the Internet and includes the applicable Internet address provided that enrollees with disabilities who cannot access this information online are provided auxiliary aids and services upon request at no cost; or

(iv) Provides the information by any other method that can reasonably be expected to result in the enrollee receiving that information.

(4) The MCO, PIHP, PAHP, or PCCM entity must give each enrollee notice of any change that the State defines as significant in the information specified in this paragraph (g), at least 30 days before the intended effective date of the change.

(h) *Information for all enrollees of MCOs, PIHPs, PAHPs, and PCCM entities—Provider Directory.* (1) Each MCO, PIHP, PAHP, and when appropriate, the PCCM entity, must make available in electronic or paper form, the following information about its network providers:

(i) The provider's name as well as any group affiliation.

(ii) Street address(es).

(iii) Telephone number(s).

(iv) Web site URL as appropriate.

(v) Specialty, if appropriate.

(vi) Whether the provider will accept new enrollees.

(vii) The provider's cultural and linguistic capabilities, including languages spoken by the provider or by skilled medical interpreter at the provider's office.

(viii) Whether the provider's office/facility is accessible for people with physical disabilities, including offices, exam room(s) and equipment.

(2) The provider directory must include the information in paragraph (h)(1) of this section for each of the following provider types covered under the contract:

(i) Physicians including specialists.

(ii) Hospitals.

(iii) Pharmacies.

(iv) Behavioral health providers.

(v) LTSS providers.

(3) Information included in a paper provider directory must be updated at least monthly and electronic provider directories must be updated no later than 3 business days after the MCO, PIHP, PAHP or PCCM entity receives updated provider information.

(4) Provider directories must be made available on the MCO's, PIHP's, PAHP's, or, if applicable, PCCM entity's Web site in a machine readable file and format as specified by the Secretary.

(i) *Information for all enrollees of MCOs, PIHPs, PAHPs, and PCCM entities: Formulary.* Each MCO, PIHP, PAHP, and when appropriate, PCCM entity, must make available in electronic or paper form, the following information about its formulary:

(1) Which medications are covered (both generic and name brand).

(2) What tier each medication is on.

(3) Formulary drug lists must be made available on the MCO's, PIHP's, PAHP's, or, if applicable, PCCM entity's Web site in a machine readable file and format as specified by the Secretary.

§ 438.12 Provider discrimination prohibited.

(a) *General rules.* (1) An MCO, PIHP, or PAHP may not discriminate in the participation, reimbursement, or indemnification of any provider who is acting within the scope of his or her license or certification under applicable State law, solely on the basis of that license or certification. If an MCO, PIHP, or PAHP declines to include individual or groups of providers in its provider network, it must give the affected providers written notice of the reason for its decision.

(2) In all contracts with health care professionals, an MCO, PIHP, or PAHP must comply with the requirements specified in § 438.214.

(b) *Construction.* Paragraph (a) of this section may not be construed to—

(1) Require the MCO, PIHP, or PAHP to contract with providers beyond the number necessary to meet the needs of its enrollees;

(2) Preclude the MCO, PIHP, or PAHP from using different reimbursement amounts for different specialties or for different practitioners in the same specialty; or

(3) Preclude the MCO, PIHP, or PAHP from establishing measures that are

designed to maintain quality of services and control costs and are consistent with its responsibilities to enrollees.

§ 438.14 Requirements that apply to MCO, PIHP, PAHP, PCCM, and PCCM entity contracts involving Indians, Indian health care providers (IHCPs), and Indian managed care entities (IMCEs).

(a) *Definitions.* As used in this section, the following terms have the indicated meanings:

Indian means any individual defined at 25 U.S.C. 1603(13),1603(28), or 1679(a), or who has been determined eligible as an Indian, under 42 CFR 136.12. This means the individual:

(i) Is a member of a Federally recognized Indian tribe.

(ii) Resides in an urban center and meets one or more of the four criteria:

(A) Is a member of a tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member;

(B) Is an Eskimo or Aleut or other Alaska Native;

(C) Is considered by the Secretary of the Interior to be an Indian for any purpose; or

(D) Is determined to be an Indian under regulations promulgated by the Secretary;

(iii) Is considered by the Secretary of the Interior to be an Indian for any purpose;

(iv) Is considered by the Secretary of Health and Human Services to be an Indian for purposes of eligibility for Indian health care services, including as a California Indian, Eskimo, Aleut, or other Alaska Native.

Indian health care provider (IHCP) under 42 CFR 447.51 means a health care program operated by the Indian Health Service (IHS) or by an Indian Tribe, Tribal Organization, or Urban Indian Organization (otherwise known as an I/T/U) as those terms are defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603).

Indian managed care entity (IMCE) under section 1932(h)(4)(B) of the Act means a MCO, PIHP, PAHP, PCCM, or PCCM entity that is controlled (within the meaning of the last sentence of section 1903(m)(1)(C) of the Act) by the Indian Health Service, a Tribe, Tribal Organization, or Urban Indian Organization, or a consortium, which may be composed of one or more Tribes, Tribal Organizations, or Urban Indian Organizations, and which also may include the Service.

(b) *Network requirements.* All contracts between a State and a MCO, PIHP, PAHP, PCCM, and PCCM entity, to the extent that the PCCM or PCCM entity has a provider network, which enroll Indians must:

(1) Require the MCO, PIHP, PAHP, PCCM entity to demonstrate that there are sufficient IHCPs participating in the provider network of the MCO, PIHP, PAHP, or PCCM entity to ensure timely access to services available under the contract from such providers for Indian enrollees who are eligible to receive services.

(2) Require that IHCPs, whether participating or not, be paid for covered services provided to Indian enrollees who are eligible to receive services from such providers as follows:

(i) At a rate negotiated between the MCO, PIHP, PAHP, PCCM, or PCCM entity, and the IHCP, or

(ii) In the absence of a negotiated rate, at a rate not less than the level and amount of payment that the MCO, PIHP, PAHP, or PCCM entity would make for the services to a participating provider which is not an IHCP; and

(iii) Make payment to all IHCPs in its network in a timely manner as required for payments to practitioners in individual or group practices under §§ 447.45 and 447.46 of this chapter.

(3) Permit any Indian who is enrolled in a MCO, PIHP, PAHP, PCCM or PCCM entity that is not an IMCE and eligible to receive services from a IHCP primary care provider participating as a network provider, to choose that IHCP as his or her primary care provider, as long as that provider has capacity to provide the services.

(4) Permit Indian enrollees to obtain services covered under the contract between the State and the MCO, PIHP, PAHP, PCCM, or PCCM entity from out-of-network IHCPs from whom the enrollee is otherwise eligible to receive such services.

(5) In a State where timely access to covered services cannot be ensured due to few or no IHCPs, an MCO, PIHP, PAHP and PCCM will be considered to have met the requirement in paragraph (b)(1) of this section if—

(i) Indian enrollees are permitted by the MCO, PIHP, PAHP, or PCCM entity to access out-of-State IHCPs; or

(ii) If this circumstance is deemed to be good cause for disenrollment from both the MCO, PIHP, PAHP, or PCCM entity and the State's managed care program in accordance with § 438.56(c).

(c) *Payment requirements.* (1) When an IHCP is enrolled in Medicaid as a FQHC but not a participating provider of the MCO, PIHP, PAHP and PCCM entity, it must be paid an amount equal to the amount the MCO, PIHP, PAHP, or PCCM entity would pay a FQHC that is a network provider but is not an IHCP, including any supplemental payment from the State to make up the difference between the amount the MCO, PIHP, PAHP or PCCM entity pays and what the IHCP FQHC would have received under FFS.

(2) When an IHCP is not enrolled in Medicaid as a FQHC, regardless of whether it participates in the network of an MCO, PIHP, PAHP and PCCM entity or not, it has the right to receive the same amount it would be paid if the services provided to the Indian enrollee were provided under the State plan in a FFS payment methodology or the applicable encounter rate published annually in the **Federal Register** by the Indian Health Service.

(3) Where the amount a IHCP receives from a MCO, PIHP, PAHP, or PCCM entity is less than the amount required by paragraph (c)(2) of this section, the State must make a supplemental payment to the IHCP to make up the difference between the amount the MCO, PIHP, PAHP, PCCM, or PCCM entity pays and the amount the IHCP would have received under FFS or the applicable encounter rate.

(d) *Enrollment in IMCEs.* An IMCE may restrict its enrollment to Indians in the same manner as Indian Health Programs may restrict the delivery of services to Indians, without being in violation of the requirements in § 438.3(d).

Subpart B—State Responsibilities

§ 438.50 State Plan requirements.

(a) *General rule.* A State plan that requires Medicaid beneficiaries to enroll in MCOs, PCCMs, or PCCM entities must comply with the provisions of this section, except when the State imposes the requirement—

(1) As part of a demonstration project under section 1115 of the Act; or

(2) Under a waiver granted under section 1915(b) of the Act.

(b) *State plan information.* The plan must specify—

(1) The types of entities with which the State contracts.

(2) The payment method it uses (for example, whether FFS or capitation).

(3) Whether it contracts on a comprehensive risk basis.

(4) The process the State uses to involve the public in both design and initial implementation of the managed care program and the methods it uses to ensure ongoing public involvement once the State plan has been implemented.

(c) *State plan assurances.* The plan must provide assurances that the State meets applicable requirements of the following statute and regulations:

(1) Section 1903(m) of the Act, for MCOs and MCO contracts.

(2) Section 1905(t) of the Act, for PCCMs and PCCM or PCCM entity contracts.

(3) Section 1932(a)(1)(A) of the Act, for the State's option to limit freedom of choice by requiring beneficiaries to receive their benefits through managed care entities.

(4) This part, for MCOs, PCCMs, and PCCM entities.

(5) Part 434 of this chapter, for all contracts.

(6) Section 438.4, for payments under any risk contracts, and § 447.362 of this chapter for payments under any nonrisk contracts.

(d) *Limitations on enrollment.* The State must provide assurances that, in implementing the State plan managed care option, it will not require the following groups to enroll in an MCO, PCCM or PCCM entity:

(1) Beneficiaries who are also eligible for Medicare.

(2) Indians as defined in § 438.14(a), except as permitted under § 438.14(d).

(3) Children under 19 years of age who are—

(i) Eligible for SSI under Title XVI;

(ii) Eligible under section 1902(e)(3) of the Act;

(iii) In foster care or other out-of-home placement;

(iv) Receiving foster care or adoption assistance; or

(v) Receiving services through a family-centered, community-based, coordinated care system that receives grant funds under section 501(a)(1)(D) of Title V, and is defined by the State in terms of either program participation or special health care needs.

§ 438.52 Choice of MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities.

(a) *General rule.* Except as specified in paragraphs (b) and (c) of this section, a State that requires Medicaid beneficiaries to:

(1) Enroll in an MCO, PIHP, or PAHP must give those beneficiaries a choice of at least two MCOs, PIHPs, or PAHPs.

(2) Enroll in a primary care case management system must give those beneficiaries a choice from at least two primary care case managers employed or contracted with the State.

(3) Enroll in a PCCM entity may limit a beneficiary to a single PCCM entity. Beneficiaries must be permitted to choose from at least two primary care case managers employed by or contracted with the PCCM entity.

(b) *Exception for rural area residents.* (1) Under any managed care program authorized by any of the following, and subject to the requirements of paragraph (b)(2) of this section, a State may limit a rural area resident to a single MCO, PIHP, or PAHP:

(i) A State plan amendment under section 1932(a) of the Act.

(ii) A waiver under section 1115 of the Act.

(iii) A waiver under section 1915(b) of the Act.

(2) To comply with this paragraph, a State, must permit the beneficiary—

(i) To choose from at least two primary care providers; and

(ii) To obtain services from any other provider under any of the following circumstances:

(A) The service or type of provider (in terms of training, experience, and specialization) is not available within the MCO, PIHP, or PAHP network.

(B) The provider is not part of the network, but is the main source of a service to the beneficiary, provided that—

(1) The provider is given the opportunity to become a participating provider under the same requirements for participation in the MCO, PIHP, or PAHP network as other network providers of that type.

(2) If the provider chooses not to join the network, or does not meet the necessary qualification requirements to join, the enrollee will be transitioned to a participating provider within 60 calendar days (after being given an opportunity to select a provider who participates).

(C) The only plan or provider available to the beneficiary does not, because of moral or religious objections, provide the service the enrollee seeks.

(D) The beneficiary's primary care provider or other provider determines that the beneficiary needs related services that would subject the beneficiary to unnecessary risk if received separately (for example, a cesarean section and a tubal ligation) and not all of the related services are available within the network.

(E) The State determines that other circumstances warrant out-of-network treatment.

(3) As used in this paragraph (b), ''rural area'' is any county designated as ''micro,'' ''rural,'' or ''County with Extreme Access Criteria (CEAC)'' in the Medicare Advantage Health Services Delivery (HSD) Reference file for the applicable calendar year.

(c) *Exception for certain health insuring organizations (HIOs).* The State may limit beneficiaries to a single HIO if—

(1) The HIO is one of those described in section 1932(a)(3)(C) of the Act; and

(2) The beneficiary who enrolls in the HIO has a choice of at least two primary care providers within the entity.

(d) *Limitations on changes between primary care providers.* For an enrollee of a single MCO, PIHP, PAHP, or HIO under paragraph (b) or (c) of this section, any limitation the State imposes on his or her freedom to change between primary care providers may be no more restrictive than the limitations on disenrollment under § 438.56(c).

§ 438.54 Managed care enrollment.

(a) *Applicability.* The provisions of this section apply to all Medicaid managed care programs which operate under any authority in the Act.

(b) *General rule.* The State must have an enrollment system for both voluntary and mandatory managed care programs.

(1) Voluntary managed care programs are those where one or more groups of beneficiaries as enumerated in section of 1905(a) of the Act have the option to either enroll in a MCO, PIHP, PAHP, PCCM or PCCM entity, or remain enrolled in FFS to receive Medicaid covered benefits.

(2) Mandatory managed care programs are those where one or more groups of beneficiaries as enumerated in section 1905(a) of the Act must enroll in a MCO, PIHP, PAHP, PCCM or PCCM entity to receive covered Medicaid benefits.

(c) *Voluntary managed care programs.* (1) States must have an enrollment system for a voluntary managed care program. That system may provide an enrollment choice period with the ability to make an active choice for managed care programs or may employ a passive enrollment process in which the State selects a MCO, PIHP, PAHP, PCCM or PCCM entity for a potential enrollee in a MCO, PIHP, PAHP, PCCM or PCCM entity but provides a period of time for the potential enrollee to decline the MCO, PIHP, PAHP, PCCM or PCCM entity selected for them before being enrolled in the MCO, PIHP, PAHP, PCCM or PCCM entity.

(2) A State must provide potential enrollees at least 14 calendar days of FFS coverage to provide the potential enrollee the opportunity to actively elect to receive covered services through the managed care or FFS delivery system. If the potential enrollee elects to receive covered services through the managed care delivery system, the potential enrollee must then also select a MCO, PIHP, PAHP, PCCM, or PCCM entity.

(i) If the State does not use a passive enrollment process and the potential enrollee does not make an active choice during the choice period, the potential enrollee will be enrolled in a MCO, PIHP, PAHP, PCCM, or PCCM entity by the State using its default process. The enrollment into the MCO, PIHP, PAHP,

PCCM, or PCCM entity will become effective after the end of the choice period.

(ii) If the State used a passive enrollment process, the potential enrollee must select either to accept the MCO, PIHP, PAHP, PCCM, or PCCM entity selected for them by the State's passive enrollment process or select a different MCO, PIHP, PAHP, PCCM, or PCCM entity. If the potential enrollee does not make an active choice during the choice period, the MCO, PIHP, PAHP, PCCM, or PCCM entity selected for them by the passive enrollment process will become effective. The enrollment into the MCO, PIHP, PAHP, PCCM, or PCCM entity will become effective after the end of the choice period.

(3) The State must develop informational notices that clearly explain the implications to the potential enrollee of not making an active choice between managed care and FFS and declining the MCO, PIHP, PAHP, PCCM, or PCCM entity selected by the State, if relevant to the State's managed care program. These notices must:

(i) Comply with the information requirements in § 438.10.

(ii) Have a postmark or electronic date stamp that is at least 3 calendar days prior to the first day of the election period identified in paragraph (c)(2) of this section.

(4) Priority for enrollment. The State's enrollment system must provide that beneficiaries already enrolled in an MCO, PIHP, PAHP, PCCM or PCCM entity are given priority to continue that enrollment if the MCO, PIHP, PAHP, PCCM or PCCM entity does not have the capacity to accept all those seeking enrollment under the program.

(5) If a State elects to use a passive enrollment process, the process must assign beneficiaries to a qualified MCO, PIHP, PAHP, PCCM or PCCM entity. To be a qualified MCO, PIHP, PAHP, PCCM or PCCM entity, it must:

(i) Not be subject to the intermediate sanction described in § 438.702(a)(4).

(ii) Have capacity to enroll beneficiaries.

(6) A passive enrollment process must seek to preserve existing provider-beneficiary relationships and relationships with providers that have traditionally served Medicaid beneficiaries.

(i) An ''existing provider-beneficiary relationship'' is one in which the provider was the main source of Medicaid services for the beneficiary during the previous year. This may be established through State records of previous managed care enrollment or FFS experience, encounter data, or through contact with the beneficiary.

(ii) A provider is considered to have ''traditionally served'' Medicaid beneficiaries if it has experience in serving the Medicaid population.

(7) If the approach in paragraph (c)(6) of this section is not possible, the State must distribute the beneficiaries equitably among the MCOs, PIHPs, PAHPs, PCCMs and PCCM entities.

(i) The State may not arbitrarily exclude any MCO, PIHP, PAHP, PCCM or PCCM entity from being considered.

(ii) The State may consider additional criteria to conduct the passive enrollment process, including the enrollment preferences of family members, previous plan assignment of the beneficiary, quality assurance and improvement performance, procurement evaluation elements, accessibility of provider offices for people with disabilities (when appropriate), and other reasonable criteria that support the objectives of the managed care program.

(8) If a passive selection process is used, the State must send a confirmation of the enrollee's managed care enrollment to the enrollee within 5 calendar days of the MCO, PIHP, PAHP, PCCM or PCCM entity enrollment being processed by the State. The confirmation must clearly explain the enrollee's right to disenroll within 90 days from the effective date of the enrollment.

(d) *Mandatory managed care programs.* (1) States must have an enrollment system for a mandatory managed care program that includes the elements specified in paragraphs (d)(2) through (7) of this section.

(2) A State must provide potential enrollees at least 14 calendar days of FFS coverage to provide the potential enrollee the opportunity to actively select their MCO, PIHP, PAHP, PCCM, or PCCM entity.

(3) A State must provide informational notices to each potential enrollee that explain the process for enrolling in a MCO, PIHP, PAHP, PCCM or PCCM entity including the choice of MCOs, PIHPs, PAHPs, PCCMs or PCCM entities available, how to make the enrollee's selection of a MCO, PIHP, PAHP or PCCM known to the State, and enrollee's right to disenroll within 90 days from the effective date of the enrollment. These notices must:

(i) Comply with the information requirements in § 438.10.

(ii) Have a postmark or electronic date stamp that is at least 3 calendar days prior to the first day of the election period identified in paragraph (d)(2) of this section.

(4) *Priority for enrollment.* The State's enrollment system must provide that beneficiaries already enrolled in an MCO, PIHP, PAHP, PCCM or PCCM entity are given priority to continue that enrollment if the MCO, PIHP, PAHP, PCCM or PCCM entity does not have the capacity to accept all those seeking enrollment under the program.

(5) *Enrollment by default.* For potential enrollees that do not select an MCO, PIHP, PAHP, PCCM or PCCM entities during the enrollment period specified in paragraph (d)(2) of this section, the State must have a default enrollment process for assigning those beneficiaries to qualified MCOs, PIHPs, PAHPs, PCCMs and PCCM entities. To be a qualified MCO, PIHP, PAHP, PCCM or PCCM entity, it must:

(i) Not be subject to the intermediate sanction described in § 438.702(a)(4).

(ii) Have capacity to enroll beneficiaries.

(6) The process must seek to preserve existing provider-beneficiary relationships and relationships with providers that have traditionally served Medicaid beneficiaries.

(i) An ''existing provider-beneficiary relationship'' is one in which the provider was the main source of Medicaid services for the beneficiary during the previous year. This may be established through State records of previous managed care enrollment or FFS experience, encounter data, or through contact with the beneficiary.

(ii) A provider is considered to have ''traditionally served'' Medicaid beneficiaries if it has experience in serving the Medicaid population.

(7) If the approach in paragraph (d)(6) of this section is not possible, the State must distribute the beneficiaries equitably among the MCOs, PIHPs, PAHPs, PCCMs and PCCM entities available to enroll them.

(i) The State may not arbitrarily exclude any MCO, PIHP, PAHP, PCCM or PCCM entity from being considered; and

(ii) The State may consider additional criteria to conduct the default enrollment process, including the enrollment preferences of family members, previous plan assignment of the beneficiary, quality assurance and improvement performance, procurement evaluation elements, and other reasonable criteria related to a beneficiary's experience with the Medicaid program.

§ 438.56 Disenrollment: Requirements and limitations.

(a) *Applicability.* The provisions of this section apply to all managed care programs whether enrollment is

mandatory or voluntary and whether the contract is with an MCO, PIHP, PAHP, PCCM or PCCM entity.

(b) *Disenrollment requested by the MCO, PIHP, PAHP, PCCM or PCCM* entity. All MCO, PIHP, PAHP, PCCM and PCCM entity contracts must:

(1) Specify the reasons for which the MCO, PIHP, PAHP, PCCM or PCCM entity may request disenrollment of an enrollee.

(2) Provide that the MCO, PIHP, PAHP, PCCM or PCCM entity may not request disenrollment because of an adverse change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs (except when his or her continued enrollment in the MCO, PIHP, PAHP, PCCM or PCCM entity seriously impairs the entity's ability to furnish services to either this particular enrollee or other enrollees).

(3) Specify the methods by which the MCO, PIHP, PAHP, PCCM or PCCM entity assures the agency that it does not request disenrollment for reasons other than those permitted under the contract.

(c) *Disenrollment requested by the enrollee.* If the State chooses to limit disenrollment, its MCO, PIHP, PAHP, PCCM and PCCM entity contracts must provide that a beneficiary may request disenrollment as follows:

(1) For cause, at any time.

(2) Without cause, at the following times:

(i) During the 90 days following the date of the beneficiary's initial enrollment into a MCO, PIHP, PAHP, PCCM or PCCM entity, or the date the State sends the beneficiary notice of the enrollment, whichever is later.

(ii) At least once every 12 months thereafter.

(iii) Upon automatic reenrollment under paragraph (g) of this section, if the temporary loss of Medicaid eligibility has caused the beneficiary to miss the annual disenrollment opportunity.

(iv) When the State imposes the intermediate sanction specified in § 438.702(a)(4).

(d) *Procedures for disenrollment*—(1) *Request for disenrollment.* The beneficiary (or his or her representative) must submit an oral or written request, as required by the State—

(i) To the State (or its agent); or

(ii) To the MCO, PIHP, PAHP, PCCM or PCCM entity, if the State permits MCOs, PIHP, PAHPs, PCCMs and PCCM entities to process disenrollment requests.

(2) *Cause for disenrollment.* The following are cause for disenrollment:

(i) The enrollee moves out of the MCO's, PIHP's, PAHP's, PCCM's or PCCM entity's service area.

(ii) The plan does not, because of moral or religious objections, cover the service the enrollee seeks.

(iii) The enrollee needs related services (for example, a cesarean section and a tubal ligation) to be performed at the same time; not all related services are available within the provider network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

(iv) For enrollees that use MLTSS services, the enrollee would have to change their residential, institutional, or employment supports provider based on that provider's change in status from an in-network to an out-of-network provider with the MCO, PIHP or PAHP.

(v) Other reasons, including poor quality of care, lack of access to services covered under the contract, or lack of access to providers experienced in dealing with the enrollee's health care needs.

(3) *MCO, PIHP, PAHP, PCCM, or PCCM entity action on request.* (i) When the MCO's, PIHP's, PAHP's, PCCM's or PCCMs entity's contract with the State permits the MCO, PIHP, PAHP, PCCM or PCCM entity to process disenrollment requests, the MCO, PIHP, PAHP, PCCM or PCCM entity may either approve a request for disenrollment by or on behalf of an enrollee or the MCO, PIHP, PAHP, PCCM or PCCM entity must refer the request to the State.

(ii) If the MCO, PIHP, PAHP, PCCM, PCCM entity, or State agency (whichever is responsible) fails to make a disenrollment determination so that the beneficiary can be disenrolled within the timeframes specified in paragraph (e)(1) of this section, the disenrollment is considered approved.

(4) *State agency action on request.* For a request received directly from the beneficiary, or one referred by the MCO, PIHP, PAHP, PCCM, or PCCM entity, the State agency must take action to approve or disapprove the request based on the following:

(i) Reasons cited in the request.

(ii) Information provided by the MCO, PIHP, PAHP, PCCM, or PCCM entity at the agency's request.

(iii) Any of the reasons specified in paragraph (d)(2) of this section.

(5) *Use of the MCO's, PIHP's, PAHP's, PCCM's or PCCMs entity's grievance procedures.* (i) The State agency may require that the enrollee seek redress through the MCO's, PIHP's, PAHP's, PCCM's or PCCM entity's grievance system before making a determination on the enrollee's request.

(ii) The grievance process, if used, must be completed in time to permit the disenrollment (if approved) to be effective in accordance with the timeframe specified in paragraph (e)(1) of this section.

(iii) If, as a result of the grievance process, the MCO, PIHP, PAHP, PCCM or PCCM entity approves the disenrollment, the State agency is not required to make a determination in accordance with paragraph (d)(4) of this section.

(e) *Timeframe for disenrollment determinations.* (1) Regardless of the procedures followed, the effective date of an approved disenrollment must be no later than the first day of the second month following the month in which the enrollee requests disenrollment or the MCO, PIHP, PAHP, PCCM or PCCM entity refers the request to the State.

(2) If the MCO, PIHP, PAHP, PCCM, PCCM entity, or the State agency (whichever is responsible) fails to make the determination within the timeframes specified in paragraph (e)(1) of this section, the disenrollment is considered approved for the effective date that would have been established had the State or MCO, PIHP, PAHP, PCCM, PCCM entity complied with paragraph (e)(1) of this section.

(f) *Notice and appeals.* A State that restricts disenrollment under this section must take the following actions:

(1) Provide that enrollees and their representatives are given written notice of disenrollment rights at least 60 days before the start of each enrollment period.

(2) Ensure timely access to State fair hearing for any enrollee dissatisfied with a State agency determination that there is not good cause for disenrollment.

(g) *Automatic reenrollment: Contract requirement.* If the State plan so specifies, the contract must provide for automatic reenrollment of a beneficiary who is disenrolled solely because he or she loses Medicaid eligibility for a period of 2 months or less.

§ 438.58 Conflict of interest safeguards.

As a condition for contracting with MCOs, PIHPs, or PAHPs, a State must have in effect safeguards against conflict of interest on the part of State and local officers and employees and agents of the State who have responsibilities relating to the MCO, PIHP, or PAHP contracts or the enrollment processes specified in § 438.54(b). These safeguards must be at least as effective as the safeguards specified in section 27 of the Office of

Federal Procurement Policy Act (41 U.S.C. 423).

§ 438.60 Prohibition of additional payments for services covered under MCO, PIHP or PAHP contracts.

The State agency must ensure that no payment is made to a network provider other than by the MCO, PIHP, or PAHP for services covered under the contract between the State and the MCO, PIHP, or PAHP, except when these payments are specifically required to be made by the State in Title XIX of the Act, in 42 CFR, or when the State agency has adjusted the capitation rates paid under the contract to account for payments for graduate medical education, in accordance with § 438.6(b)(4).

§ 438.62 Continued services to enrollees.

(a) The State agency must arrange for Medicaid services to be provided without delay to any Medicaid enrollee of an MCO, PIHP, PAHP, PCCM or PCCM entity the contract of which is terminated and for any Medicaid enrollee who is disenrolled from an MCO, PIHP, PAHP, PCCM or PCCM entity for any reason other than ineligibility for Medicaid.

(b) The State must have in effect a transition of care policy to ensure continued access to services during a transition from FFS to a MCO, PIHP, PAHP, PCCM or PCCM entity or transition from one MCO, PIHP, PAHP, PCCM or PCCM entity to another when an enrollee, in the absence of continued services, would suffer serious detriment to their health or be at risk of hospitalization or institutionalization.

(1) The transition of care policy must include the following:

(i) The enrollee has access to services consistent with the access they previously had, and is permitted to retain their current provider for a period of time if that provider is not in the MCO, PIHP or PAHP network.

(ii) The enrollee is referred to appropriate providers of services that are in the network.

(iii) The State, in the case of FFS, PCCM, or PCCM entity, or the MCO, PIHP or PAHP that was previously serving the enrollee, fully and timely complies with requests for historical utilization data from the new MCO, PIHP, PAHP, PCCM, or PCCM entity in compliance with Federal and State law.

(iv) Consistent with Federal and State law, the enrollee's new provider(s) are able to obtain copies of the enrollee's medical records, as appropriate.

(v) Any other necessary procedures as specified by the Secretary to ensure continued access to services to prevent serious detriment to the enrollee's health or reduce the risk of hospitalization or institutionalization.

(2) The State must require by contract that MCOs, PIHPs, and PAHPs implement a transition of care policy consistent with the requirements in paragraph (b)(1) of this section and at least meets the State defined transition of care policy.

(3) The State must make its transition of care policy publicly available and provide instructions to enrollees and potential enrollees on how to access continued services upon transition. At a minimum the transition of care policy must be described in the comprehensive quality strategy, as required by § 438.340, and explained to individuals in the materials to enrollees and potential enrollees, in accordance with § 438.10.

§ 438.66 State monitoring requirements.

(a) *General requirement.* The State agency must have in effect a monitoring system for all managed care programs.

(b) The State's system must address all aspects of the managed care program, including the performance of each MCO, PIHP, PAHP and PCCM entity (if applicable) in at least the following areas:

(1) Administration and management.

(2) Appeal and grievance systems.

(3) Claims management.

(4) Enrollee materials and customer services.

(5) Finance, including medical loss ratio reporting.

(6) Information systems, including encounter data reporting.

(7) Marketing.

(8) Medical management, including utilization management and case management.

(9) Program integrity.

(10) Provider network management.

(11) Availability and accessibility of services.

(12) Quality improvement.

(13) Areas related to the delivery of LTSS not otherwise included in paragraphs (b)(1) through (12) of this section as applicable to the managed care program.

(14) All other provisions of the contract, as appropriate.

(c) The State must use data collected from its monitoring activities to improve the performance of its managed care program, including at a minimum:

(1) Enrollment and disenrollment trends in each MCO, PIHP, or PAHP.

(2) Member grievance and appeal logs.

(3) Provider complaint and appeal logs.

(4) Findings from the State's External Quality Review process.

(5) Results from any enrollee satisfaction survey conducted by the State or MCO, PIHP or PAHP.

(6) Performance on required quality measures.

(7) Medical management committee reports and minutes.

(8) The annual quality improvement plan for each MCO, PIHP, PAHP, or PCCM entity.

(9) Audited financial and encounter data submitted by each MCO, PIHP or PAHP.

(10) The medical loss ratio summary reports required by § 438.8.

(11) Customer service performance data submitted by each MCO, PIHP or PAHP.

(12) Any other data related to the provision of LTSS not otherwise included in paragraphs (c)(1) through (11) of this section as applicable to the managed care program.

(d)(1) The State must assess the readiness of each MCO, PIHP, PAHP or PCCM entity with which it contracts as follows:

(i) Prior to the State implementing a managed care program, whether the program is voluntary or mandatory.

(ii) When the specific MCO, PIHP, PAHP or PCCM entity has not previously contracted with the State.

(iii) When any MCO, PIHP, PAHP or PCCM entity currently contracting with the State will provide or arrange for the provisions of covered benefits to new eligibility groups.

(iv) When any MCO, PIHP, PAHP or PCCM entity currently contracting with the State will provide a new set of benefits to current or new eligibility groups; or

(v) When any MCO, PIHP, PAHP or PCCM entity currently contacting with the State will expand coverage to new geographic areas.

(2) The State must conduct a readiness review of each MCO, PIHP, PAHP, or PCCM entity with which it contracts as follows:

(i) Started at least 3 months prior to the effective date of the events described in paragraph (d)(1) of this section.

(ii) Completed in sufficient time to ensure smooth implementation of an event described in paragraph (d)(1) of this section.

(iii) Submitted to CMS in order for CMS to make a determination that the contract or contract amendment associated with an event described in paragraph (d)(1) of this section is approved under § 438.3.

(3) Readiness reviews must include both a desk review of documents and on-site reviews of each MCO, PIHP, PAHP or PCCM entity. On-site reviews must include interviews with MCO,

PIHP, PAHP or PCCM entity staff and leadership that manage key operational areas.

(4) A State's readiness review must assess the ability and capacity of the MCO, PIHP, PAHP and PCCM entity (if applicable) to perform satisfactorily for the following areas:

(i) Operations/Administration, including—

(A) Administrative staffing and resources.

(B) Delegation and oversight of MCO, PIHP, PAHP or PCCM entity responsibilities.

(C) Enrollee and provider communications.

(D) Grievance and appeals.

(E) Member services and outreach.

(F) Provider Network Management.

(G) Program Integrity/Compliance.

(ii) Service delivery, including—

(A) Case management/care coordination/Service planning.

(B) Quality improvement.

(C) Utilization review.

(iii) Financial management, including—

(A) Financial reporting and monitoring.

(B) Financial solvency.

(iv) Systems management, including—

(A) Claims management.

(B) Encounter data and enrollment information management.

(e)(1) The State must submit to CMS no later than 150 days after each contract year, a report on each managed care program administered by the State, regardless of the authority under which the program operates. For States that operate their managed care program under section 1115 of the Act authority, submission of an annual report that may be required by the Special Terms and Conditions of the demonstration program will be deemed to satisfy the requirement of this paragraph provided that the report includes the information specified in paragraph (e)(2) of this section.

(2) The program report must provide information on and an assessment of the operation of the managed care program and include, at a minimum, the following:

(i) Financial performance of each MCO, PIHP and PAHP.

(ii) Encounter data reporting by each MCO, PIHP or PAHP.

(iii) Enrollment and service area expansion (if applicable) of each MCO, PIHP, PAHP and PCCM entity.

(iv) Modifications to, and implementation of, MCO, PIHP, or PAHP benefits covered under the contract with the State.

(v) Grievance, appeals and State fair hearings for the managed care program.

(vi) Availability and accessibility of covered services within the MCO, PIHP, or PAHP contracts.

(vii) Evaluation of MCO, PIHP, or PAHP performance on quality measures, including as applicable, consumer report card, surveys, or other reasonable measures of performance.

(viii) Results of any sanctions or corrective action plans imposed by the State or other formal or informal intervention with a contracted MCO, PIHP, PAHP or PCCM entity to improve performance.

(ix) Any other factors in the delivery of LTSS not otherwise addressed in (e)(2)(i)–(viii) of this section as applicable.

(3) The program report required in this section must be:

(i) Posted on the Web site required under § 438.10.

(ii) Provided to the Medical Care Advisory Committee, required under § 431.12 of this chapter.

(iii) Provided to the stakeholder consultation group specified in § 438.70, to the extent that the managed care program includes LTSS.

§ 438.68 Network adequacy standards.

(a) *General rule.* A State that contracts with an MCO, PIHP or PAHP to deliver Medicaid services must develop and enforce network adequacy standards consistent with this section.

(b) *Provider-specific network adequacy standards.* (1) At a minimum, a State must develop time and distance standards for the following provider types, if covered under the contract:

(i) Primary care, adult and pediatric.

(ii) OB/GYN.

(iii) Behavioral health.

(iv) Specialist, adult and pediatric.

(v) Hospital.

(vi) Pharmacy.

(vii) Pediatric dental.

(viii) Additional provider types when it promotes the objectives of the Medicaid program, as determined by CMS, for the provider type to be subject to time and distance access standards.

(2) *LTSS.* States with MCO, PIHP or PAHP contracts which cover LTSS must develop:

(i) Time and distance standards for LTSS provider types in which an enrollee must travel to the provider to receive services; and

(ii) Network adequacy standards other than time and distance standards for LTSS provider types that travel to the enrollee to deliver services.

(3) *Scope of network adequacy standards.* Network standards established in accordance with paragraphs (b)(1) and (b)(2) of this section must include all geographic areas covered by the managed care program or, if applicable, the contract between the State and the MCO, PIHP or PAHP. States are permitted to have varying standards for the same provider type based on geographic areas.

(c) *Development of network adequacy standards.* (1) States developing network adequacy standards consistent with paragraph (b)(1) of this section must consider, at a minimum, the following elements:

(i) The anticipated Medicaid enrollment.

(ii) The expected utilization of services.

(iii) The characteristics and health care needs of specific Medicaid populations covered in the MCO, PIHP, and PAHP contract.

(iv) The numbers and types (in terms of training, experience, and specialization) of network health care professionals required to furnish the contracted Medicaid services.

(v) The numbers of network health care professionals who are not accepting new Medicaid patients.

(vi) The geographic location of health care professionals and Medicaid enrollees, considering distance, travel time, the means of transportation ordinarily used by Medicaid enrollees.

(vii) The ability of health care professionals to communicate with limited English proficient enrollees in their preferred language.

(viii) The ability of healthcare professionals to ensure physical access, reasonable accommodations, culturally competent communications, and accessible equipment for Medicaid enrollees with physical or mental disabilities.

(2) States developing standards consistent with paragraph (b)(2) of this section must consider the following:

(i) All elements in paragraphs (c)(1)(i) through (viii) of this section.

(ii) Elements that would support an enrollee's choice of provider.

(iii) Strategies that would ensure the health and welfare of the enrollee and support community integration of the enrollee.

(iv) Other considerations that are in the best interest of the enrollees that need LTSS.

(d) *Exceptions process.* (1) To the extent the State permits an exception to any of the provider-specific network standards developed under this section, the standard by which the exception will be evaluated and approved must be:

(i) Specified in the MCO, PIHP or PAHP contract.

(ii) Based, at a minimum, on the number of health care professionals in that specialty practicing in the MCO, PIHP, or PAHP service area.

(2) States that grant an exception in accordance with paragraph (d)(1) of this section to a MCO, PIHP or PAHP must monitor enrollee access to that provider type on an ongoing basis and include the findings to CMS in the managed care program assessment report required under § 438.66.

(e) *Publication of network adequacy standards.* States must publish the standards developed in accordance with paragraphs (b)(1) and (b)(2) of this section on the Web site required by § 438.10. Upon request, network adequacy standards must also be made available at no cost to enrollees with disabilities in alternate formats or through the provision of auxiliary aids and services.

§ 438.70 Stakeholder engagement when LTSS is delivered through a managed care program.

The State must ensure the views of beneficiaries, providers, and other stakeholders are solicited and addressed during the design, implementation, and oversight of a State's managed LTSS program. The composition of the stakeholder group and frequency of meetings must be sufficient to ensure meaningful stakeholder engagement.

§ 438.71 Beneficiary support system.

(a) *General requirement.* The State must develop and implement a beneficiary support system that provides support to beneficiaries both prior to and after enrollment in a MCO, PIHP, PAHP, PCCM or PCCM entity.

(b) *Elements of the support system.* (1) A State beneficiary support system must include at a minimum:

(i) Choice counseling for all beneficiaries.

(ii) Training for network providers as specified in paragraph (d) of this section.

(iii) Assistance for enrollees in understanding managed care.

(iv) Assistance for enrollees who use, or express a desire to receive, LTSS as specified in paragraph (e) of this section.

(2) The beneficiary support system must perform outreach to beneficiaries and/or authorized representatives and be accessible in multiple ways including phone, Internet, in-person, and via auxiliary aids and services when requested.

(c) *Choice counseling.* (1) Choice counseling, as defined in § 438.2, must be provided to all potential enrollees and enrollees who disenroll from a MCO, PIHP, PAHP, PCCM or PCCM entity for reasons specified in § 438.56(b) and (c).

(2) If an individual or entity provides choice counseling on the State's behalf under a memorandum of agreement or contract, it is considered an enrollment broker as defined in § 438.810(a) and must meet the independence and freedom from conflict of interest standards in § 438.810(b)(1) and (2).

(d) *Training.* The beneficiary support system must provide training to MCOs, PIHPs, PAHPs, PCCMs, PCCM entities and network providers on community-based resources and supports that can be linked with covered benefits.

(e) *Functions specific to LTSS activities.* At a minimum, the beneficiary support system must provide the following support to enrollees who use, or express a desire to receive, LTSS:

(1) An access point for complaints and concerns about MCO, PIHP, PAHP, PCCM, and PCCM entity enrollment, access to covered services, and other related matters.

(2) Education on enrollees' grievance and appeal rights within the MCO, PIHP or PAHP; the State fair hearing process; enrollee rights and responsibilities; and additional resources outside of the MCO, PIHP or PAHP.

(3) Assistance, upon request, in navigating the grievance and appeal process within the MCO, PIHP or PAHP, as well as appealing adverse benefit determinations by the MCO, PIHP, or PAHP to a State fair hearing. The system may not provide representation to the enrollee at a State fair hearing but may refer enrollees to sources of legal representation.

(i) An entity that receives non-Medicaid funding to represent beneficiaries at hearings, may, subject to approval by CMS, establish firewalls to provide choice counseling as an independent function.

(ii) [Reserved].

(4) Review and oversight of LTSS program data to provide guidance to the State Medicaid Agency on identification, remediation and resolution of systemic issues.

§ 438.74 State oversight of the minimum MLR requirement.

(a) *State reporting requirement.* (1) The State must annually submit to CMS a summary description of the report(s) received from the MCO(s), PIHP(s), and PAHP(s) under contract with the State under § 438.8(k) with the actuarial certification described in § 438.7.

(2) The summary description must include, at a minimum, the amount of the numerator, denominator, MLR experienced, the number of member months, and any remittances owed by each MCO, PIHP, or PAHP for that MLR reporting year.

(b) *Repayment of Federal share of remittances.* (1) If a State requires a MCO, PIHP, or PAHP to pay remittances through the contract for not meeting the minimum MLR required by the State, the State must reimburse CMS for an amount equal to the Federal share of the remittance, taking into account applicable differences in Federal matching rate.

(2) If a remittance is owed according to paragraph (b)(1) of this section, the State must submit a report describing the methodology used to determine the State and Federal share of the remittance with the report required in paragraph (a) of this section.

Subpart C—Enrollee Rights and Protections

§ 438.100 Enrollee rights.

(a) *General rule.* The State must ensure that:

(1) Each MCO, PIHP, PAHP, PCCM and PCCM entity has written policies regarding the enrollee rights specified in this section; and

(2) Each MCO, PIHP, PAHP, PCCM and PCCM entity complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its employees and contracted providers observe and protect those rights.

(b) *Specific rights.* (1) *Basic requirement.* The State must ensure that each managed care enrollee is guaranteed the rights as specified in paragraphs (b)(2) and (b)(3) of this section.

(2) An enrollee of an MCO, PIHP, PAHP, PCCM or PCCM entity has the following rights: The right to—

(i) Receive information in accordance with § 438.10.

(ii) Be treated with respect and with due consideration for his or her dignity and privacy.

(iii) Receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollee's condition and ability to understand. (The information requirements for services that are not covered under the contract because of moral or religious objections are set forth in § 438.10(g)(2)(ii)(A) and (B).

(iv) Participate in decisions regarding his or her health care, including the right to refuse treatment.

(v) Be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience or retaliation, as specified in other Federal regulations on the use of restraints and seclusion.

(vi) If the privacy rule, as set forth in 45 CFR parts 160 and 164 subparts A

and E, applies, request and receive a copy of his or her medical records, and request that they be amended or corrected, as specified in 45 CFR 164.524 and 164.526.

(3) An enrollee of an MCO, PIHP, or PAHP has the right to be furnished health care services in accordance with §§ 438.206 through 438.210.

(c) *Free exercise of rights.* The State must ensure that each enrollee is free to exercise his or her rights, and that the exercise of those rights does not adversely affect the way the MCO, PIHP, PAHP, PCCM or PCCM entity and its network providers or the State agency treat the enrollee.

(d) *Compliance with other Federal and State laws.* The State must ensure that each MCO, PIHP, PAHP, PCCM and PCCM entity complies with any other applicable Federal and State laws (including: Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 80; the Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91; the Rehabilitation Act of 1973; and Titles II and III of the Americans with Disabilities Act).

§ 438.102 Provider-enrollee communications.

(a) *General rules.* (1) An MCO, PIHP, or PAHP may not prohibit, or otherwise restrict, a health care professional acting within the lawful scope of practice, from advising or advocating on behalf of an enrollee who is his or her patient, for the following:

(i) The enrollee's health status, medical care, or treatment options, including any alternative treatment that may be self-administered.

(ii) Any information the enrollee needs to decide among all relevant treatment options.

(iii) The risks, benefits, and consequences of treatment or nontreatment.

(iv) The enrollee's right to participate in decisions regarding his or her health care, including the right to refuse treatment, and to express preferences about future treatment decisions.

(2) Subject to the information requirements of paragraph (b) of this section, an MCO, PIHP, or PAHP that would otherwise be required to provide, reimburse for, or provide coverage of, a counseling or referral service because of the requirement in paragraph (a)(1) of this section is not required to do so if the MCO, PIHP, or PAHP objects to the service on moral or religious grounds.

(b) *Information requirements: MCO, PIHP, and PAHP responsibility.* (1) An MCO, PIHP, or PAHP that elects the option provided in paragraph (a)(2) of this section must furnish information about the services it does not cover as follows:

(i) To the State—

(A) With its application for a Medicaid contract.

(B) Whenever it adopts the policy during the term of the contract.

(ii) Consistent with the provisions of § 438.10—

(A) To potential enrollees, before and during enrollment.

(B) To enrollees, within 90 days after adopting the policy for any particular service.

(Although this timeframe would be sufficient to entitle the MCO, PIHP, or PAHP to the option provided in paragraph (a)(2) of this section, the overriding rule in § 438.10(g)(4) requires the State, its contracted representative, or MCO, PIHP, or PAHP to furnish the information at least 30 days before the effective date of the policy.)

(2) As specified in § 438.10(g)(2)(ii)(A) and (B), the information that MCOs, PIHPs, and PAHPs must furnish to enrollees and potential enrollees does not include how and where to obtain the service excluded under paragraph (a)(2) of this section.

(c) *Information requirements: State responsibility.* For each service excluded by an MCO, PIHP, or PAHP under paragraph (a)(2) of this section, the State must provide information on how and where to obtain the service, as specified in § 438.10.

(d) *Sanction.* An MCO that violates the prohibition of paragraph (a)(1) of this section is subject to intermediate sanctions under subpart I of this part.

§ 438.104 Marketing activities.

(a) *Definitions.* As used in this section, the following terms have the indicated meanings:

Cold-call marketing means any unsolicited personal contact by the MCO, PIHP, PAHP, PCCM or PCCM entity with a potential enrollee for the purpose of marketing as defined in this paragraph (a).

Marketing means any communication, from an MCO, PIHP, PAHP, PCCM or PCCM entity to a Medicaid beneficiary who is not enrolled in that entity, that can reasonably be interpreted as intended to influence the beneficiary to enroll in that particular MCO's, PIHP's, PAHP's, PCCM's or PCCM entity's Medicaid product, or either to not enroll in, or to disenroll from, another MCO's, PIHP's, PAHP's, PCCM's or PCCM entity's Medicaid product. Marketing does not include communication to a Medicaid beneficiary from the issuer of a qualified health plan, as defined in 45 CFR 155.20, about the qualified health plan.

Marketing materials means materials that—

(1) Are produced in any medium, by or on behalf of an MCO, PIHP, PAHP, or PCCM; and

(2) Can reasonably be interpreted as intended to market the MCO, PIHP, PAHP, PCCM or PCCM entity to potential enrollees.

MCO, PIHP, PAHP, PCCM or PCCM entity include any of the entity's employees, network providers, agents, or contractors.

Private insurance does not include a qualified health plan, as defined in 45 CFR 155.20.

(b) *Contract requirements.* Each contract with an MCO, PIHP, PAHP, PCCM or PCCM entity must comply with the following requirements:

(1) Provide that the entity—

(i) Does not distribute any marketing materials without first obtaining State approval.

(ii) Distributes the materials to its entire service area as indicated in the contract.

(iii) Complies with the information requirements of § 438.10 to ensure that, before enrolling, the beneficiary receives, from the entity or the State, the accurate oral and written information he or she needs to make an informed decision on whether to enroll.

(iv) Does not seek to influence enrollment in conjunction with the sale or offering of any private insurance.

(v) Does not, directly or indirectly, engage in door-to-door, telephone, email, texting, or other cold-call marketing activities.

(2) Specify the methods by which the entity ensures the State agency that marketing, including plans and materials, is accurate and does not mislead, confuse, or defraud the beneficiaries or the State agency. Statements that will be considered inaccurate, false, or misleading include, but are not limited to, any assertion or statement (whether written or oral) that—

(i) The beneficiary must enroll in the MCO, PIHP, PAHP, PCCM or PCCM entity to obtain benefits or to not lose benefits; or

(ii) The MCO, PIHP, PAHP, PCCM or PCCM entity is endorsed by CMS, the Federal or State government, or similar entity.

(c) *State agency review.* In reviewing the marketing materials submitted by the entity, the State must consult with the Medical Care Advisory Committee established under § 431.12 of this chapter or an advisory committee with similar membership.

§ 438.106 Liability for payment.

Each MCO, PIHP, and PAHP must provide that its Medicaid enrollees are not held liable for any of the following:

(a) The MCO's, PIHP's, or PAHP's debts, in the event of the entity's insolvency.

(b) Covered services provided to the enrollee, for which—

(1) The State does not pay the MCO, PIHP, or PAHP; or

(2) The State, or the MCO, PIHP, or PAHP does not pay the individual or health care provider that furnished the services under a contractual, referral, or other arrangement.

(c) Payments for covered services furnished under a contract, referral, or other arrangement, to the extent that those payments are in excess of the amount that the enrollee would owe if the MCO, PIHP, or PAHP covered the services directly.

§ 438.108 Cost sharing.

The contract must provide that any cost sharing imposed on Medicaid enrollees is in accordance with §§ 447.50 through 447.82 of this chapter.

§ 438.110 Member advisory committee.

(a) *General rule.* When LTSS are covered under a risk contract between a State and an MCO, PIHP, or PAHP, the contract must provide that each MCO, PIHP or PAHP establish and maintain a member advisory committee.

(b) *Committee composition.* The committee required in paragraph (a) of this section must include at least a reasonably representative sample of the LTSS populations covered under the contract with the MCO, PIHP, or PAHP.

§ 438.114 Emergency and poststabilization services.

(a) *Definitions.* As used in this section—

Emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in the following:

(i) Placing the health of the individual (or, for a pregnant woman, the health of the woman or her unborn child) in serious jeopardy.

(ii) Serious impairment to bodily functions.

(iii) Serious dysfunction of any bodily organ or part.

Emergency services means covered inpatient and outpatient services that are as follows:

(i) Furnished by a provider that is qualified to furnish these services under this title.

(ii) Needed to evaluate or stabilize an emergency medical condition.

Poststabilization care services means covered services, related to an emergency medical condition that are provided after an enrollee is stabilized to maintain the stabilized condition, or, under the circumstances described in paragraph (e) of this section, to improve or resolve the enrollee's condition.

(b) *Coverage and payment: General rule.* The following entities are responsible for coverage and payment of emergency services and poststabilization care services.

(1) The MCO, PIHP, or PAHP.

(2) The State, for managed care programs that contract with PCCMs or PCCM entities

(c) *Coverage and payment: Emergency services*—(1) The entities identified in paragraph (b) of this section—

(i) Must cover and pay for emergency services regardless of whether the provider that furnishes the services has a contract with the MCO, PIHP, PAHP, PCCM or PCCM entity; and

(ii) May not deny payment for treatment obtained under either of the following circumstances:

(A) An enrollee had an emergency medical condition, including cases in which the absence of immediate medical attention would not have had the outcomes specified in paragraphs (1), (2), and (3) of the definition of emergency medical condition in paragraph (a) of this section.

(B) A representative of the MCO, PIHP, PAHP, PCCM or PCCM entity instructs the enrollee to seek emergency services.

(2) A PCCM or PCCM entity must allow enrollees to obtain emergency services outside the primary care case management system regardless of whether the case manager referred the enrollee to the provider that furnishes the services.

(d) *Additional rules for emergency services.* (1) The entities specified in paragraph (b) of this section may not—

(i) Limit what constitutes an emergency medical condition with reference to paragraph (a) of this section, on the basis of lists of diagnoses or symptoms; and

(ii) Refuse to cover emergency services based on the emergency room provider, hospital, or fiscal agent not notifying the enrollee's primary care provider, MCO, PIHP, PAHP or applicable State entity of the enrollee's screening and treatment within 10 calendar days of presentation for emergency services.

(2) An enrollee who has an emergency medical condition may not be held liable for payment of subsequent screening and treatment needed to diagnose the specific condition or stabilize the patient.

(3) The attending emergency physician, or the provider actually treating the enrollee, is responsible for determining when the enrollee is sufficiently stabilized for transfer or discharge, and that determination is binding on the entities identified in paragraph (b) of this section as responsible for coverage and payment.

(e) *Coverage and payment: Poststabilization care services.* Poststabilization care services are covered and paid for in accordance with provisions set forth at § 422.113(c) of this chapter. In applying those provisions, reference to ''MA organization'' and ''financially responsible'' must be read as reference to the entities responsible for Medicaid payment, as specified in paragraph (b) of this section, and payment rules governed by Title XIX of the Act and the States.

(f) *Applicability to PIHPs and PAHPs.* To the extent that services required to treat an emergency medical condition fall within the scope of the services for which the PIHP or PAHP is responsible, the rules under this section apply.

§ 438.116 Solvency standards.

(a) *Requirement for assurances* (1) Each MCO, PIHP, and PAHP that is not a Federally qualified HMO (as defined in section 1310 of the Public Health Service Act) must provide assurances satisfactory to the State showing that its provision against the risk of insolvency is adequate to ensure that its Medicaid enrollees will not be liable for the MCO's, PIHP's, or PAHP's debts if the entity becomes insolvent.

(2) Federally qualified HMOs, as defined in section 1310 of the Public Health Service Act, are exempt from this requirement.

(b) *Other requirements.* (1) *General rule.* Except as provided in paragraph (b)(2) of this section, an MCO or PIHP, must meet the solvency standards established by the State for private health maintenance organizations, or be licensed or certified by the State as a risk-bearing entity.

(2) *Exception.* Paragraph (b)(1) of this section does not apply to an MCO or PIHP that meets any of the following conditions:

(i) Does not provide both inpatient hospital services and physician services.

(ii) Is a public entity.

(iii) Is (or is controlled by) one or more Federally qualified health centers

and meets the solvency standards established by the State for those centers.

(iv) Has its solvency guaranteed by the State.

Subpart D—MCO, PIHP and PAHP Standards

§ 438.206 Availability of services.

(a) *Basic rule.* Each State must ensure that all services covered under the State plan are available and accessible to enrollees of MCOs, PIHPs, and PAHPs in a timely manner. The State must also ensure that MCO, PIHP and PAHP provider networks for services covered under the contract meet the standards developed by the State in accordance with § 438.68.

(b) *Delivery network.* The State must ensure, through its contracts, that each MCO, PIHP and PAHP, consistent with the scope of its contracted services, meets the following requirements:

(1) Maintains and monitors a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to all services covered under the contract for all enrollees, including those with limited English proficiency or physical or mental disabilities.

(2) Provides female enrollees with direct access to a women's health specialist within the provider network for covered care necessary to provide women's routine and preventive health care services. This is in addition to the enrollee's designated source of primary care if that source is not a women's health specialist.

(3) Provides for a second opinion from a qualified health care professional within the provider network, or arranges for the enrollee to obtain one outside the network, at no cost to the enrollee.

(4) If the provider network is unable to provide necessary services, covered under the contract, to a particular enrollee, the MCO, PIHP, or PAHP must adequately and timely cover these services out of network for the enrollee, for as long as the MCO, PIHP, or PAHP's provider network is unable to provide them.

(5) Requires out-of-network providers to coordinate with the MCO, PIHP, or PAHP for payment and ensures the cost to the enrollee is no greater than it would be if the services were furnished within the network.

(6) Demonstrates that its network providers are credentialed as required by § 438.214.

(c) *Furnishing of services.* The State must ensure that each contract with a MCO, PIHP, and PAHP complies with the following requirements.

(1) *Timely access.* Each MCO, PIHP, and PAHP must do the following:

(i) Meet and require its network providers to meet State standards for timely access to care and services, taking into account the urgency of the need for services.

(ii) Ensure that the network providers offer hours of operation that are no less than the hours of operation offered to commercial enrollees or comparable to Medicaid FFS, if the provider serves only Medicaid enrollees.

(iii) Make services included in the contract available 24 hours a day, 7 days a week, when medically necessary.

(iv) Establish mechanisms to ensure compliance by network providers.

(v) Monitor network providers regularly to determine compliance.

(vi) Take corrective action if there is a failure to comply by a network provider.

(2) *Access and cultural considerations.* Each MCO, PIHP, and PAHP participates in the State's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds, disabilities, and regardless of gender, sexual orientation or gender identity.

(3) *Accessibility considerations.* Each MCO, PIHP, and PAHP must ensure that network providers provide physical access, accommodations, and accessible equipment for Medicaid enrollees with physical or mental disabilities.

§ 438.207 Assurances of adequate capacity and services.

(a) *Basic rule.* The State must ensure, through its contracts, that each MCO, PIHP, and PAHP gives assurances to the State and provides supporting documentation that demonstrates that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care under this subpart.

(b) *Nature of supporting documentation.* Each MCO, PIHP, and PAHP must submit documentation to the State, in a format specified by the State to demonstrate that it complies with the following requirements:

(1) Offers an appropriate range of preventive, primary care, specialty services, and LTSS that is adequate for the anticipated number of enrollees for the service area.

(2) Maintains a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area.

(c) *Timing of documentation.* Each MCO, PIHP, and PAHP must submit the documentation described in paragraph (b) of this section as specified by the State, but no less frequently than the following:

(1) At the time it enters into a contract with the State.

(2) On an annual basis.

(3) At any time there has been a significant change (as defined by the State) in the MCO's, PIHP's, or PAHP's operations that would affect the adequacy of capacity and services, including—

(i) Changes in MCO, PIHP, or PAHP services, benefits, geographic service area, composition of or payments to its provider network; or

(ii) Enrollment of a new population in the MCO, PIHP, or PAHP.

(d) *State review and certification to CMS.* After the State reviews the documentation submitted by the MCO, PIHP, or PAHP, the State must submit an assurance of compliance to CMS that the MCO, PIHP, or PAHP meets the State's requirements for availability of services, as set forth in § 438.206. The submission to CMS must include documentation of an analysis that supports the assurance of the adequacy of the network for each contracted MCO, PIHP or PAHP related to its provider network.

(e) *CMS' right to inspect documentation.* The State must make available to CMS, upon request, all documentation collected by the State from the MCO, PIHP, or PAHP.

§ 438.208 Coordination and continuity of care.

(a) *Basic requirement.* (1) *General rule.* Except as specified in paragraphs (a)(2) and (a)(3) of this section, the State must ensure through its contracts, that each MCO, PIHP, and PAHP complies with the requirements of this section.

(2) *PIHP and PAHP exception.* For PIHPs and PAHPs, the State determines, based on the scope of the entity's services, and on the way the State has organized the delivery of managed care services, whether a particular PIHP or PAHP is required to implement mechanisms for identifying, assessing, and producing a treatment plan for an individual with special health care needs, as specified in paragraph (c) of this section.

(3) *Exception for MCOs that serve dually eligible enrollees.* (i) For each MCO that serves enrollees who are also enrolled in and receive Medicare benefits from a Medicare Advantage Organization, the State determines to what extent the MCO must meet the identification, assessment, and treatment planning provisions of

paragraph (c) of this section for dually eligible individuals.

(ii) The State bases its determination on the needs of the population it requires the MCO to serve.

(b) *Care and coordination of services for all MCO, PIHP, and PAHP enrollees.* Each MCO, PIHP, and PAHP must implement procedures to deliver care to and coordinate services for all MCO, PIHP, and PAHP enrollees. These procedures must meet State requirements and must do the following:

(1) Ensure that each enrollee has an ongoing source of care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the services accessed by the enrollee.

(2) Coordinate the services the MCO, PIHP, or PAHP furnishes to the enrollee:

(i) Between settings of care including appropriate discharge planning for short term and long-term hospital and institutional stays;

(ii) With the services the enrollee receives from any other MCO, PIHP, or PAHP; and

(iii) With the services the enrollee receives in FFS Medicaid.

(3) Provide that the MCO, PIHP or PAHP, within 90 days of the effective date of enrollment for all new enrollees, makes a best effort to conduct an initial assessment of each enrollee's needs, including subsequent attempts if the initial attempt to contact the enrollee is unsuccessful.

(4) Share with the State or other MCOs, PIHPs, and PAHP serving the enrollee the results of any identification and assessment of that enrollee's needs to prevent duplication of those activities.

(5) Ensure that each provider furnishing services to enrollees maintains and shares, as appropriate, an enrollee health record in accordance with professional standards.

(6) Ensure that in the process of coordinating care, each enrollee's privacy is protected in accordance with the privacy requirements in 45 CFR parts 160 and 164 subparts A and E, to the extent that they are applicable.

(c) *Additional services for enrollees with special health care needs or who need LTSS.* (1) *Identification.* The State must implement mechanisms to identify persons who need LTSS or persons with special health care needs to MCOs, PIHPs and PAHPs, as those persons are defined by the State. These identification mechanisms—

(i) Must be specified in the State's comprehensive quality strategy in § 438.340.

(ii) May use State staff, the State's enrollment broker, or the State's MCOs, PIHPs and PAHPs.

(2) *Assessment.* Each MCO, PIHP, and PAHP must implement mechanisms to comprehensively assess each Medicaid enrollee identified by the State (through the mechanism specified in paragraph (c)(1) of this section) and identified to the MCO, PIHP, and PAHP by the State as needing LTSS or having special health care needs to identify any ongoing special conditions of the enrollee that require a course of treatment or regular care monitoring. The assessment mechanisms must use appropriate health care professionals or individuals meeting LTSS service coordination requirements of the State or the MCO, PIHP, or PAHP as appropriate.

(3) *Treatment/service plans.* If the State requires MCOs, PIHPs, or PAHPs to produce a treatment or service plan for enrollees who require LTSS or with special health care needs that are determined through assessment to need a course of treatment or regular care monitoring, the treatment or service plan must be—

(i) Developed by the enrollee's provider or individual meeting LTSS service coordination requirements with enrollee participation, and in consultation with any other health care professionals caring for the enrollee.

(ii) Developed by a person trained in person centered planning using a person-centered process and plan as defined in § 441.301(c)(1) and (2) of this chapter for LTSS treatment or service plans.

(iii) Approved by the MCO, PIHP, or PAHP in a timely manner, if this approval is required by the MCO, PIHP, or PAHP.

(iv) In accord with any applicable State quality assurance and utilization review standards.

(v) Reviewed and revised upon reassessment of functional need, at least every 12 months, or when the enrollee's circumstances or needs change significantly, or at the request of the enrollee per section § 441.301(c)(3) of this chapter.

(4) *Direct access to specialists.* For enrollees with special health care needs determined through an assessment by appropriate health care professionals (consistent with paragraph (c)(2) of this section) to need a course of treatment or regular care monitoring, each MCO, PIHP, and PAHP must have a mechanism in place to allow enrollees to directly access a specialist (for example, through a standing referral or an approved number of visits) as appropriate for the enrollee's condition and identified needs.

§ 438.210 Coverage and authorization of services.

(a) *Coverage.* Each contract between a State and an MCO, PIHP, or PAHP must do the following:

(1) Identify, define, and specify the amount, duration, and scope of each service that the MCO, PIHP, or PAHP is required to offer.

(2) Require that the services identified in paragraph (a)(1) of this section be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to beneficiaries under FFS Medicaid, as set forth in § 440.230 of this chapter.

(3) Provide that the MCO, PIHP, or PAHP—

(i) Must ensure that the services are sufficient in amount, duration, or scope to reasonably achieve the purpose for which the services are furnished.

(ii) May not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of diagnosis, type of illness, or condition of the beneficiary.

(4) Permit an MCO, PIHP, or PAHP to place appropriate limits on a service—

(i) On the basis of criteria applied under the State plan, such as medical necessity; or

(ii) For the purpose of utilization control, provided that

(A) The services furnished can reasonably achieve their purpose, as required in paragraph (a)(3)(i) of this section;

(B) The services supporting individuals with ongoing or chronic conditions or who require long-term services and supports are authorized in a manner that reflects the enrollee's ongoing need for such services and supports; and

(C) Family planning services are provided in a manner that protects and enables the enrollee's freedom to choose the method of family planning to be used consistent with § 441.20.

(5) Specify what constitutes ''medically necessary services'' in a manner that—

(i) Is no more restrictive than that used in the State Medicaid program as indicated in State statutes and regulations, the State Plan, and other State policy and procedures;

(ii) Meets the requirements for providing early and periodic screening and diagnosis of beneficiaries under age 21 to ascertain physical and mental defects, and treatment to correct or ameliorate defects and chronic conditions found (EPSDT); and

(iii) Addresses the extent to which the MCO, PIHP, or PAHP is responsible for covering services that address:

(A) The prevention, diagnosis, and treatment of an enrollee's disease, condition, and/or disorder that results in health impairments and/or disability.

(B) The ability for an enrollee to achieve age-appropriate growth and development.

(C) The ability for an enrollee to attain, maintain, or regain functional capacity.

(D) The opportunity for an enrollee receiving long-term services and supports to have access to the benefits of community living.

(b) *Authorization of services.* For the processing of requests for initial and continuing authorizations of services, each contract must require—

(1) That the MCO, PIHP, or PAHP and its subcontractors have in place, and follow, written policies and procedures.

(2) That the MCO, PIHP, or PAHP—

(i) Have in effect mechanisms to ensure consistent application of review criteria for authorization decisions.

(ii) Consult with the requesting provider for medical services when appropriate.

(iii) Authorize LTSS based on an enrollee's current needs assessment and consistent with the person-centered service plan.

(3) That any decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested, be made by a health care professional who has appropriate expertise in addressing the enrollee's medical, behavioral health, or long-term services and supports needs.

(c) *Notice of adverse benefit determination.* Each contract must provide for the MCO, PIHP, or PAHP to notify the requesting provider, and give the enrollee written notice of any decision by the MCO, PIHP, or PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. For MCOs, PIHPs, and PAHPs the notice must meet the requirements of § 438.404.

(d) *Timeframe for decisions.* Each MCO, PIHP, or PAHP contract must provide for the following decisions and notices:

(1) *Standard authorization decisions.* For standard authorization decisions, provide notice as expeditiously as the enrollee's condition requires and within State-established timeframes that may not exceed 14 calendar days following receipt of the request for service, with a possible extension of up to 14 additional calendar days, if—

(i) The enrollee, or the provider, requests extension; or

(ii) The MCO, PIHP, or PAHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(2) *Expedited authorization decisions.* (i) For cases in which a provider indicates, or the MCO, PIHP, or PAHP determines, that following the standard timeframe could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function, the MCO, PIHP, or PAHP must make an expedited authorization decision and provide notice as expeditiously as the enrollee's health condition requires and no later than 72 hours after receipt of the request for service.

(ii) The MCO, PIHP, or PAHP may extend the 72 hour time period by up to 14 calendar days if the enrollee requests an extension, or if the MCO, PIHP, or PAHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(e) *Compensation for utilization management activities.* Each contract between a State and MCO, PIHP, or PAHP must provide that, consistent with § 438.3(i), and § 422.208 of this chapter, compensation to individuals or entities that conduct utilization management activities is not structured so as to provide incentives for the individual or entity to deny, limit, or discontinue medically necessary services to any enrollee.

§ 438.214 Provider selection.

(a) *General rules.* The State must ensure, through its contracts, that each MCO, PIHP, or PAHP implements written policies and procedures for selection and retention of providers and that those policies and procedures, at a minimum, meet the requirements of this section.

(b) *Credentialing and recredentialing requirements.* (1) Each State must establish a uniform credentialing and recredentialing policy that addresses acute, primary, behavioral, substance use disorders, and LTSS providers, as appropriate, and require each MCO, PIHP and PAHP to follow those policies.

(2) Each MCO, PIHP, and PAHP must follow a documented process for credentialing and recredentialing of providers who have signed contracts or participation agreements with the MCO, PIHP, or PAHP.

(c) *Nondiscrimination.* MCO, PIHP, and PAHP provider selection policies and procedures, consistent with § 438.12, must not discriminate against particular providers that serve high-risk populations or specialize in conditions that require costly treatment.

(d) *Excluded providers.* (1) MCOs, PIHPs, and PAHPs may not employ or contract with providers excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act.

(e) *State requirements.* Each MCO, PIHP, and PAHP must comply with any additional requirements established by the State.

§ 438.224 Confidentiality.

The State must ensure, through its contracts, that (consistent with subpart F of part 431 of this chapter), for medical records and any other health and enrollment information that identifies a particular enrollee, each MCO, PIHP, and PAHP uses and discloses such individually identifiable health information in accordance with the privacy requirements in 45 CFR parts 160 and 164, subparts A and E, to the extent that these requirements are applicable.

§ 438.228 Grievance systems.

(a) The State must ensure, through its contracts, that each MCO, PIHP, and PAHP has in effect a grievance system that meets the requirements of subpart F of this part.

(b) If the State delegates to the MCO, PIHP, or PAHP responsibility for notice of action under subpart E of part 431 of this chapter, the State must conduct random reviews of each delegated MCO, PIHP, or PAHP and its providers and subcontractors to ensure that they are notifying enrollees in a timely manner.

§ 438.230 Subcontractual relationships and delegation.

(a) *Applicability.* The requirements of this section apply to any contract or written arrangement that an MCO, PIHP, or PAHP has with any individual or entity that relates directly or indirectly to the performance of the MCO's PIHP's or PAHP's obligations under its contract with the State.

(b) *General rule.* The State must ensure, through its contracts with MCOs, PIHPs, and PAHPs, that—

(1) Notwithstanding any relationship(s) that the MCO, PIHP, or PAHP may have with any other individual or entity, the MCO, PIHP, or PAHP maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with the State; and

(2) All contracts or written arrangements between the MCO, PIHP, or PAHP and any individual or entity

that relates directly or indirectly to the performance of the MCO's PIHP's or PAHP's activities or obligations under its contract with the State must meet the requirements of paragraph (c) of this section.

(c) Each contract or written arrangement described in paragraph (b)(2) of this section must specify that:

(1) If any of the MCO's, PIHP's, or PAHP's activities or obligations under its contract with the State are delegated to another individual or entity—

(i) The delegated activities or obligations, and related reporting responsibilities, are specified in the contract or written agreement.

(ii) The individual or entity agrees to perform the delegated activities and reporting responsibilities specified in compliance with the MCO's, PIHP's or PAHP's contract obligations.

(iii) The contract or written arrangement must either provide for revocation of the delegation of activities or obligations, or specify other remedies in instances where the State or the MCO, PIHP, or PAHP determine that the individual or entity has not performed satisfactorily.

(2) The individual or entity agrees to comply with all applicable Medicaid laws, regulations, subregulatory guidance, and contract provisions;

(3) The individual or entity agrees that—

(i) The State, CMS, the HHS Inspector General, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, computer or other electronic systems of the individual or entity, or of the individual's or entity's contractor or subcontractor, that pertain to any aspect of services and activities performed, or determination of amounts payable under the contract with the State, if the reasonable possibility of fraud is determined to exist by any of these entities.

(ii) The individual or entity will make available, for purposes of an audit, evaluation, or inspection under paragraph (c)(3)(i) of this section, its premises, physical facilities, equipment, and records relating to its Medicaid enrollees.

(iii) The right to audit under paragraph (c)(3)(i) of this section will exist through 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(iv) If the State, CMS, or the HHS Inspector General determines that there is a reasonable possibility of fraud or similar risk, the State, CMS, or the HHS Inspector General may inspect, evaluate, and audit the individual or entity at any time.

§ 438.236 Practice guidelines.

(a) *Basic rule.* The State must ensure, through its contracts, that each MCO, PIHP, and PAHP meets the requirements of this section.

(b) *Adoption of practice guidelines.* Each MCO and, when applicable, each PIHP and PAHP adopts practice guidelines that meet the following requirements:

(1) Are based on valid and reliable clinical evidence or a consensus of health care professionals in the particular field.

(2) Consider the needs of the MCO's, PIHP's, or PAHP's enrollees.

(3) Are adopted in consultation with contracting health care professionals.

(4) Are reviewed and updated periodically as appropriate.

(c) *Dissemination of guidelines.* Each MCO, PIHP, and PAHP disseminates the guidelines to all affected providers and, upon request, to enrollees and potential enrollees.

(d) *Application of guidelines.* Decisions for utilization management, enrollee education, coverage of services, and other areas to which the guidelines apply are consistent with the guidelines.

§ 438.242 Health information systems.

(a) *General rule.* The State must ensure, through its contracts that each MCO, PIHP, and PAHP maintains a health information system that collects, analyzes, integrates, and reports data and can achieve the objectives of this part. The systems must provide information on areas including, but not limited to, utilization, claims, grievances and appeals, and disenrollments for other than loss of Medicaid eligibility.

(b) *Basic elements of a health information system.* The State must require, at a minimum, that each MCO, PIHP, and PAHP comply with the following:

(1) Section 6504(a) of the Affordable Care Act, which requires that State claims processing and retrieval systems are able to collect data elements necessary to enable the mechanized claims processing and information retrieval systems in operation by the State to meet the requirements of section 1903(r)(1)(F) of the Act.

(2) Collect data on enrollee and provider characteristics as specified by the State, and on all services furnished to enrollees through an encounter data system or other methods as may be specified by the State.

(3) Ensure that data received from providers is accurate and complete by—

(i) Verifying the accuracy and timeliness of reported data, including data from network providers the MCO, PIHP, or PAHP is compensating on the basis of capitation payments.

(ii) Screening the data for completeness, logic, and consistency.

(iii) Collecting data from providers in standardized formats to the extent feasible and appropriate, including secure information exchanges and technologies utilized for State Medicaid quality improvement and care coordination efforts.

(4) Make all collected data available to the State and upon request to CMS, as required in this part.

(c) *Enrollee encounter data.* Contracts between a State and a MCO, PIHP, or PAHP must provide for:

(1) Collection and maintenance of sufficient enrollee encounter data to identify the provider who delivers any item(s) or service(s) to enrollees.

(2) Submission of enrollee encounter data to the State at a frequency and level of detail to be specified by CMS.

(3) Submission of all enrollee encounter data that the State is required to report to CMS under § 438.818.

(4) Specifications for submitting encounter data to the State in standardized ASC X12N 837 and NCPDP formats, and the ASC X12N 835 format as appropriate.

Subpart E—Quality Measurement and Improvement; External Quality Review

§ 438.310 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart is based on sections 1932(c)(1), 1932(c)(2), 1903(a)(3)(C)(ii), 1902(a)(4), and 1902(a)(19) of the Act.

(b) *Scope.* This subpart sets forth:

(1) Specifications for a quality assessment and performance improvement program that States must require each contracting managed care organization (MCO), prepaid inpatient health plan (PIHP), and prepaid ambulatory health plan (PAHP) to implement and maintain.

(2) Requirements for the state review and approval of all contracting MCOs, PIHPs, and PAHPs.

(3) Specifications for a Medicaid managed care quality rating system for all States contracting with MCOs, PIHPs, and PAHPs.

(4) Specifications for managed care elements of the comprehensive quality strategy that States must implement to ensure the delivery of quality health care.

(5) Requirements for annual external quality reviews of each contracting MCO, PIHP, and PAHP including—

(i) Criteria that States must use in selecting entities to perform the reviews.

(ii) Specifications for the activities related to external quality review.

(iii) Circumstances under which external quality review may use the results of Medicare quality reviews or private accreditation reviews.

(iv) Requirements for making the results of the reviews publicly available.

(c) *Applicability.* (1) The provisions of this subpart apply to MCOs, PIHPs, and PAHPs. For purposes of this subpart, HIOs that are not expressly exempt by statute are required to comply with this subpart as an MCO.

(2) PCCM entities. Notwithstanding paragraphs (b) and (c)(1) of this section, the State must assess the performance of each PCCM entity consistent with the requirements of § 438.3(r). That assessment must, at a minimum, include the elements described in § 438.330(b)(3), (c), and (e).

§ 438.320 Definitions.

As used in this subpart—

Access, as it pertains to external quality review, means the timely use of services to achieve the best outcomes possible, as evidenced by successfully demonstrating and reporting on outcome information for the availability and timeliness elements defined under § 438.68 (Network adequacy standards) and § 438.206 (Availability of services).

EQR stands for external quality review.

EQRO stands for external quality review organization.

External quality review means the analysis and evaluation by an EQRO, of aggregated information on quality, timeliness, and access to the health care services that an MCO, PIHP, or PAHP, or their contractors furnish to Medicaid beneficiaries.

External quality review organization means an organization that meets the competence and independence requirements set forth in § 438.354, and holds a contract with a State to perform external quality review, other EQR-related activities as set forth in § 438.358, or both.

Financial relationship means—

(1) A direct or indirect ownership or investment interest (including an option or nonvested interest) in any entity. This direct or indirect interest may be in the form of equity, debt, or other means, and includes any indirect ownership or investment interest no matter how many levels removed from a direct interest; or

(2) A compensation arrangement with an entity.

Quality, as it pertains to external quality review, means the degree to which an MCO, PIHP, or PAHP increases the likelihood of desired health outcomes of its enrollees through:

(1) Its structural and operational characteristics.

(2) The provision of services that are consistent with current professional, evidenced-based knowledge.

(3) Positive trends in performance measures and clinically significant results from interventions for performance improvement.

Validation means the review of information, data, and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis.

§ 438.330 Quality assessment and performance improvement program.

(a) *General rules.* (1) The State must require, through its contracts, that each MCO, PIHP, and PAHP establish and implement an ongoing comprehensive quality assessment and performance improvement program for the services it furnishes to its enrollees.

(2) CMS, through a public notice and comment process in consultation with States and other stakeholders, may specify performance measures for collection in accordance with paragraph (c) of this section, a methodology for calculating quality ratings, and topics with performance indicators for performance improvement projects in accordance with paragraph (d) of this section to be required by States in their contracts with MCOs, PIHPs, and PAHPs.

(i) In addition to those required by CMS under paragraph (a)(2) of this section, States may select their own performance improvement projects topics and performance measures to satisfy the requirements of paragraphs (b)(1) and (b)(2) of this section.

(ii) A State may apply for an exemption from collecting and reporting on the performance measures or performance improvement projects established under (a)(2) of this section, by submitting a request, in writing, to CMS which details the reason for such an exemption.

(b) *Basic elements of quality assessment and performance improvement programs.* At a minimum, the State must ensure that each MCO, PIHP, and PAHP comply with the following requirements:

(1) Conduct performance improvement projects in accordance with paragraph (d) of this section.

(2) Collect and submit performance measurement data in accordance with paragraph (c) of this section.

(3) Have in effect mechanisms to detect both underutilization and overutilization of services.

(4) Have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs, as defined by the State.

(5) Have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees using LTSS, including assessment of care between care settings and a comparison of services received with those set forth in the enrollee's treatment plan.

(6) Participate in efforts by the State to prevent, detect, and remediate critical incidents that are based, at a minimum, on the requirements on the State for home and community-based waiver programs.

(c) *Performance measurement.* Annually each MCO, PIHP, and PAHP must—

(1) Measure and report to the State its performance, using standard measures required by the State, including those performance measures specified by CMS under paragraph (a)(2) of this section.

(2) Submit to the State data, as specified by the State, that enables the State to measure the MCO's, PIHP's, or PAHP's performance; or

(3) Perform a combination of the activities described in paragraphs (c)(1) and (c)(2) of this section.

(4) *LTSS performance measurement.* The State must require, through its contracts, each MCO, PIHP, and PAHP that provides LTSS services to include, as a part of its performance measurement activities under this paragraph and in addition to other measures required of all MCOs, PIHPs, and PAHPs, measures that assess the quality of life of beneficiaries and the outcomes of the MCO, PIHP, or PAHP's rebalancing and community integration activities for beneficiaries receiving LTSS.

(d) *Performance improvement projects.* (1) MCOs, PIHPs, and PAHPs must have an ongoing program of performance improvement projects that focuses on both clinical and nonclinical areas. These projects must be designed to achieve, through ongoing measurements and intervention, significant improvement, sustained over time, in clinical care and nonclinical care areas that are expected to have a favorable effect on health outcomes and enrollee satisfaction. Each project must include the following elements:

(i) Measurement of performance using objective quality indicators.

(ii) Implementation of interventions to achieve improvement in the access to and quality of care.

(iii) Evaluation of the effectiveness of the interventions.

(iv) Planning and initiation of activities for increasing or sustaining improvement.

(2) Each MCO, PIHP, and PAHP must report the status and results of each project to the State as requested, including those topics specified by CMS under paragraph (a)(3) of this section. Each performance improvement project must be completed in a reasonable time period so as to generally allow information on the success of performance improvement projects in the aggregate to produce new information on quality of care every year.

(3) *Option for MCOs, PIHPs, or PAHPs serving only dual eligibles.* At State option, MCOs, PIHPs, or PAHPs exclusively serving dual eligibles may substitute a MA Organization quality improvement project conducted under § 422.152(d) of this chapter for a performance improvement project required under this paragraph (d)(1) of this section.

(e) *Program review by the State.* (1) The State must review, at least annually, the impact and effectiveness of each MCO's, PIHP's, and PAHP's quality assessment and performance improvement program. The review must include—

(i) The MCO's, PIHP's, and PAHP's performance on the measures on which it is required to report.

(ii) The outcomes and trended results of each MCO's, PIHP's, and PAHP's performance improvement projects.

(iii) The results of any efforts by the MCO, PIHP, or PAHP to support community integration for enrollees using LTSS.

(2) The State may require that an MCO, PIHP, or PAHP have in effect a process for its own evaluation of the impact and effectiveness of its quality assessment and performance improvement program.

§ 438.332 State review and approval of MCOs, PIHPs, and PAHPs.

(a) *General requirement.* (1) To enter into a contract with the State under this part, MCOs, PIHPs, and PAHPs must be reviewed and approved by the State on the basis of performance in accordance with standards that are at least as stringent as the standards used by a private accreditation entity recognized by CMS under 45 CFR 156.275(c) or approved under § 422.157 of this chapter.

(2) Following initial approval, the State must review and reapprove each MCO, PIHP, and PAHP in accordance with paragraph (a)(1) of this section at least once every 3 years.

(3) Upon obtaining initial State approval in accordance with paragraph (a)(1) of this section, MCOs, PIHPs, and PAHPs must perform consistent with the level required for approval so long as they participate in the State's Medicaid managed care program.

(b) *Compliance deemed on the basis of accreditation by a private independent entity.* (1) The State may elect to use proof of MCO, PIHP, or PAHP accreditation by a private independent entity recognized by CMS under 45 CFR 156.275(c) or approved under § 422.157 of this chapter to satisfy the requirement described in paragraph (a) of this section.

(2) If the State chooses to exercise this option, the MCO, PIHP, or PAHP must authorize the private accreditation entity to release to the State a copy of its most recent accreditation survey, including:

(i) Accreditation status, survey type, or level (if applicable).

(ii) Accreditation results, including recommended actions or improvements, corrective action plans, and summaries of findings.

(iii) Expiration date of accreditation.

(c) The State must make the final approval status, whether based on State review or private accreditation, for all MCOs, PIHPs, and PAHPs available on the State's Medicaid Web site required under § 438.10(c)(3).

§ 438.334 Medicaid managed care quality rating system.

(a)(1) Each State contracting with an MCO, PIHP, or PAHP must establish a quality rating system for Medicaid managed care plans that meets the requirements of this section.

(2) The quality rating system must be based on the following three components:

(i) Clinical quality management.

(ii) Member experience.

(iii) Plan efficiency, affordability, and management.

(3) The quality rating system must measure and report on the performance of each MCO, PIHP, or PAHP on measures identified by CMS, under § 438.330(a)(2). Such measures will be categorized within each of the components listed in paragraph (a)(1) of this section. The quality rating system may also measure and report on additional measures identified by the State.

(b) Each State must collect data from each MCO, PIHP, and PAHP with which it contracts, which includes, at a minimum, data evidencing the MCO's, PIHP's, or PAHP's performance on the measures described in paragraph (a)(2) of this section. The State must apply the methodology established by CMS, under § 438.330(a)(2), to these performance measures to determine a quality rating or ratings for each MCO, PIHP, or PAHP.

(c) *Alternative quality rating system.* Upon CMS approval, a State may opt to use an alternative quality rating system that utilizes different components than those described in paragraph (a)(2) of this section, incorporates the use of different performance measures than those described in paragraph (a)(3) of this section, or applies a different methodology from that described in paragraph (b) of this section.

(d) *Option for MCOs, PIHPs, or PAHPs serving only dual eligibles.* The State may opt to utilize the MA five-star rating for MCOs, PIHPs, or PAHPs exclusively serving dual eligible in place of the quality rating system established under this section.

(e) The State must prominently display on its Web site the quality rating of each MCO, PIHP, or PAHP in a manner that complies with the standards in § 438.10(d).

§ 438.340 Managed care elements of the State comprehensive quality strategy.

In addition to the requirements set forth in part 431, subpart I of this chapter, any State contracting with an MCO, PIHP, or PAHP must also address the following elements in the State's comprehensive quality strategy:

(a) The State-defined MCO, PIHP, and PAHP network adequacy and availability of services standards required by §§ 438.68 and 438.206 and examples of evidence-based clinical practice guidelines the State requires its MCOs, PIHPs, and PAHPs to adopt in accordance with § 438.236.

(b) The State's goals and objectives for continuous quality improvement must be developed in accordance with § 431.502(b)(1) of this chapter and must incorporate a description of:

(1) Quality metrics and performance targets for measuring improvement and performance regarding MCOs, PIHPs, and PAHPs, and include, at a minimum, performance measures to be reported in accordance with § 438.330(c); and

(2) Performance improvement projects to be implemented in accordance with § 438.330(d), including a description of any interventions the State proposes to achieve improvement in access, quality, or timeliness of care for enrollees in MCOs, PIHPs, and PAHPs.

(c) Arrangements for annual, external independent reviews of the quality outcomes and timeliness of, and access to, the services covered under each MCO, PIHP, and PAHP contract.

(d) For MCOs, appropriate use of intermediate sanctions that, at a

minimum, meet the requirements of subpart I of this part.

(e) A description of how the State will assess the performance and quality outcomes achieved by each PCCM entity, consistent with the requirements in § 438.3(r).

§ 438.350 External quality review.

(a) Each State that contracts with MCOs, PIHPs, or PAHPs must ensure that—

(1) Except as provided in § 438.362, a qualified EQRO performs an annual EQR for each contracting MCO, PIHP, and PAHP.

(2) The EQRO has sufficient information to use in performing the review.

(3) The information used to carry out the review must be obtained from the EQR-related activities described in § 438.358 or from a Medicare or private accreditation review as described in § 438.360.

(4) For each EQR-related activity, the information gathered for use in the EQR must include the elements described in § 438.364(a)(1)(i) through (iv).

(5) The information provided to the EQRO in accordance with paragraph (a)(2) of this section is obtained through methods consistent with the protocols established under § 438.352.

(6) The results of the reviews are made available as specified in § 438.364.

(b) A State may require that a qualified EQRO performs an annual EQR for each PCCM entity consistent with the requirements of § 438.3(r). If an EQR is performed, the requirements in paragraphs (a)(2) through (6) of this section apply.

§ 438.352 External quality review protocols.

Each protocol must specify—

(a) The data to be gathered;

(b) The sources of the data;

(c) The activities and steps to be followed in collecting the data to promote its accuracy, validity, and reliability;

(d) The proposed method or methods for validly analyzing and interpreting the data once obtained; and

(e) Instructions, guidelines, worksheets, and other documents or tools necessary for implementing the protocol.

§ 438.354 Qualifications of external quality review organizations.

(a) *General rule.* The State must ensure that an EQRO meets the requirements of this section.

(b) *Competence.* The EQRO must have at a minimum the following:

(1) Staff with demonstrated experience and knowledge of—

(i) Medicaid beneficiaries, policies, data systems, and processes;

(ii) Managed care delivery systems, organizations, and financing;

(iii) Quality assessment and improvement methods; and

(iv) Research design and methodology, including statistical analysis.

(2) Sufficient physical, technological, and financial resources to conduct EQR or EQR-related activities.

(3) Other clinical and nonclinical skills necessary to carry out EQR or EQR-related activities and to oversee the work of any subcontractors.

(c) *Independence.* The EQRO and its subcontractors are independent from the State Medicaid agency and from the MCOs, PIHPs, or PAHPs that they review. To qualify as ''independent''—

(1) A State agency, department, university, or other State entity may not have Medicaid purchasing or managed care licensing authority; and

(2) A State agency, department, university, or other State entity must be governed by a Board or similar body the majority of whose members are not government employees.

(3) An EQRO may not—

(i) Review a particular MCO, PIHP, or PAHP if either the EQRO or the MCO, PIHP, or PAHP exerts control over the other (as used in this paragraph, ''control'' has the meaning given the term in 48 CFR 19.101) through—

(A) Stock ownership;

(B) Stock options and convertible debentures;

(C) Voting trusts;

(D) Common management, including interlocking management; and

(E) Contractual relationships.

(ii) Deliver any health care services to Medicaid beneficiaries;

(iii) Conduct, on the State's behalf, ongoing Medicaid managed care program operations related to oversight of the quality of MCO, PIHP, or PAHP services, except for the related activities specified in § 438.358;

(iv) Conduct or have conducted within the previous 3 years, an accreditation review on any contracting MCO, PIHP, or PAHP; or

(v) Have a present, or known future, direct or indirect financial relationship with an MCO, PIHP, or PAHP that it will review as an EQRO.

§ 438.356 State contract options for external quality review.

(a) The State—

(1) Must contract with one EQRO to conduct either EQR alone or EQR and other EQR-related activities.

(2) May contract with additional EQROs or other entities to conduct EQR-related activities as set forth in § 438.358.

(b) Each EQRO must meet the competence requirements as specified in § 438.354(b).

(c) Each EQRO is permitted to use subcontractors. The EQRO is accountable for, and must oversee, all subcontractor functions.

(d) Each EQRO and its subcontractors performing EQR or EQR-related activities must meet the requirements for independence, as specified in § 438.354(c).

(e) For each contract with an EQRO described in paragraph (a) of this section, the State must follow an open, competitive procurement process that is in accordance with State law and regulations. In addition, the State must comply with 45 CFR part 75 as it applies to State procurement of Medicaid services.

§ 438.358 Activities related to external quality review.

(a) *General rule.* (1) The State, its agent that is not an MCO, PIHP, or PAHP, or an EQRO may perform the mandatory and optional EQR-related activities in this section.

(2) The data obtained from the mandatory and optional EQR-related activities in this section must be used as described in § 438.350(a)(3).

(b) *Mandatory activities.* For each MCO, PIHP, and PAHP, the following EQR-related activities must be performed:

(1) Validation of performance improvement projects, required by the State and CMS to comply with requirements set forth in § 438.330(b)(1), that were underway during the preceding 12 months.

(2) Validation of MCO, PIHP, or PAHP performance measures reported (as required by the State and CMS) or MCO, PIHP, or PAHP performance measures calculated by the State during the preceding 12 months to comply with requirements set forth in § 438.330(b)(2).

(3) A review, conducted within the previous 3-year period, to determine the MCO's, PIHP's, or PAHP's compliance with the standards set forth in subpart D and the quality assessment and performance improvement requirements described in § 438.330.

(4) Validation of MCO, PIHP, and PAHP network adequacy during the preceding 12 months to comply with requirements set forth in § 438.68.

(c) *Optional activities.* For each MCO, PIHP, and PAHP, the following activities may be performed by using information derived during the preceding 12 months:

(1) Validation of encounter data reported by an MCO, PIHP, or PAHP.

(2) Administration or validation of consumer or provider surveys of quality of care.

(3) Calculation of performance measures in addition to those reported by an MCO, PIHP, or PAHP and validated by an EQRO.

(4) Conduct of performance improvement projects in addition to those conducted by an MCO, PIHP, or PAHP and validated by an EQRO.

(5) Conduct of studies on quality that focus on a particular aspect of clinical or nonclinical services at a point in time.

(d) *Technical assistance.* The EQRO may, at the State's direction, provide technical guidance to groups of MCOs, PIHPs, or PAHPs to assist them in conducting activities related to the mandatory and optional activities described in this section that provide information for the EQR and the resulting EQR technical report.

§ 438.360 Nonduplication of mandatory activities.

(a) *General rule.* To avoid duplication, the State may use information about an MCO, PIHP, or PAHP obtained from a Medicare or private accreditation review to provide information otherwise obtained from the mandatory activities specified in § 438.358 if the conditions of paragraph (b) of this section are met.

(b) *MCOs, PIHPs, or PAHPs reviewed by Medicare or private accrediting organizations.* For information about an MCO's, PIHP's, or PAHP's performance for the validation of performance improvement projects (as required by § 438.358(b)(1)) or performance measures (as required by § 438.358(b)(2)) or compliance with the standards in subpart D of this part (as required by § 438.358(b)(3)), the State may use information from a Medicare or private accreditation review if the following conditions are met:

(1) The MCO, PIHP, or PAHP is in compliance with the standards established by CMS for Medicare or has obtained accreditation from a private accrediting organization recognized by CMS. The Medicare or private accreditation review standards must be substantially comparable to the mandatory activities set forth in §§ 438.358(b)(1) through (b)(3).

(2) The MCO, PIHP, or PAHP provides to the State all the reports, findings, and other results of the Medicare or private accreditation review related to the mandatory activities set forth in § 438.358(b)(1), (b)(2), and (b)(3) and the State provides the information to the EQRO. The EQRO must include an analysis and aggregation of this information in the final EQR technical report as described in § 438.364.

(c) In its comprehensive quality strategy, the State must identify the mandatory activities for which it has exercised this option and explain its rationale for why these activities are duplicative.

§ 438.362 Exemption from external quality review.

(a) *Basis for exemption.* The State may exempt an MCO from EQR if the following conditions are met:

(1) The MCO has a current Medicare contract under part C of Title XVIII or under section 1876 of the Act, and a current Medicaid contract under section 1903(m) of the Act.

(2) The two contracts cover all or part of the same geographic area within the State.

(3) The Medicaid contract has been in effect for at least 2 consecutive years before the effective date of the exemption and during those 2 years the MCO has been subject to EQR under this part, and found to be performing acceptably for the quality, timeliness, and access to health care services it provides to Medicaid beneficiaries.

(b) *Information on exempted MCOs.* When the State exercises this option, the State must obtain either of the following:

(1) *Information on Medicare review findings.* Each year, the State must obtain from each MCO that it exempts from EQR the most recent Medicare review findings reported on the MCO including—

(i) All data, correspondence, information, and findings pertaining to the MCO's compliance with Medicare standards for access, quality assessment and performance improvement, health services, or delegation of these activities.

(ii) All measures of the MCO's performance.

(iii) The findings and results of all performance improvement projects pertaining to Medicare enrollees.

(2) *Medicare information from a private, national accrediting organization that CMS approves and recognizes for MA Organization deeming.* (i) If an exempted MCO has been reviewed by a private accrediting organization, the State must require the MCO to provide the State with a copy of all findings pertaining to its most recent accreditation review if that review has been used for either of the following purposes:

(A) To fulfill certain requirements for Medicare external review under subpart D of part 422 of this chapter.

(B) To deem compliance with Medicare requirements, as provided in § 422.156 of this chapter.

(ii) These findings must include, but need not be limited to, accreditation review results of evaluation of compliance with individual accreditation standards, noted deficiencies, corrective action plans, and summaries of unmet accreditation requirements.

§ 438.364 External quality review results.

(a) *Information that must be produced.* The State must ensure that the EQR results in an annual detailed technical report that summarizes findings on access and quality of care, including:

(1) A description of the manner in which the data from all activities conducted in accordance with § 438.358 were aggregated and analyzed, and conclusions were drawn as to the quality, timeliness, and access to the care furnished by the MCO, PIHP, or PAHP. The report must also include the following for each EQR-related activity conducted in accordance with § 438.358:

(i) Objectives.

(ii) Technical methods of data collection and analysis.

(iii) Description of data obtained, including performance measurement data for each activity conducted in accordance with § 438.358(b)(1) and (2).

(iv) Conclusions drawn from the data.

(2) An assessment of each MCO's, PIHP's, or PAHP's strengths and weaknesses for the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries.

(3) Recommendations for improving the quality of health care services furnished by each MCO, PIHP, or PAHP, including how the State can target goals and objectives in the comprehensive quality strategy to better support improvement in the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries.

(4) Methodologically appropriate, comparative information about all MCOs, PIHPs, and PAHPs.

(5) An assessment of the degree to which each MCO, PIHP, or PAHP has addressed effectively the recommendations for quality improvement made by the EQRO during the previous year's EQR.

(b) *Availability of information.* (1) The State must contract with a qualified EQRO to produce and submit to the State an annual EQR technical report in accordance with paragraph (a) of this section. The annual technical report must be finalized no later than April 30th of each year. States may not

substantively revise the content of the final EQR technical report without evidence of error or omission.

(2) The State must provide copies of the information specified in paragraph (a) of this section, upon request, through print or electronic media, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO, PIHP, or PAHP, beneficiary advocacy groups, and members of the general public. The State must make the most recent copy of the annual EQR technical report publicly available on the State's Web site required under § 438.10(c)(3).

(3) The State must make the information specified in paragraph (a) of this section available in alternative formats for persons with disabilities, when requested.

(c) *Safeguarding patient identity.* The information released under paragraph (b) of this section may not disclose the identity of any patient.

§ 438.370 Federal financial participation (FFP).

(a) FFP at the 75 percent rate is available in expenditures for EQR (including the production of EQR results) and the EQR-related activities set forth in § 438.358 performed on MCOs and conducted by EQROs and their subcontractors.

(b) FFP at the 50 percent rate is available in expenditures for EQR-related activities conducted by any entity that does not qualify as an EQRO, and for EQR (including the production of EQR results) and EQR-related activities performed by an EQRO on entities other than MCOs.

(c) Prior to claiming FFP at the 75 percent rate in accordance with paragraph (a) of this section, the State must submit each EQRO contract to CMS for review and approval.

Subpart F—Grievance System

§ 438.400 Statutory basis and definitions.

(a) *Statutory basis.* This subpart is based on the following statutory sections:

(1) Section 1902(a)(3) of the Act requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly.

(2) Section 1902(a)(4) of the Act requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(3) Section 1932(b)(4) of the Act requires Medicaid managed care organizations to establish internal grievance procedures under which Medicaid enrollees, or providers acting on their behalf, may challenge the denial of coverage of, or payment for, medical assistance.

(b) *Definitions.* As used in this subpart, the following terms have the indicated meanings:

Adverse benefit determination means, in the case of an MCO, PIHP, or PAHP, any of the following:

(1) The denial or limited authorization of a requested service, including determinations based on the type or level of service, requirements for medical necessity, appropriateness, health care setting, or effectiveness of a covered benefit.

(2) The reduction, suspension, or termination of a previously authorized service.

(3) The denial, in whole or in part, of payment for a service.

(4) The failure to provide services in a timely manner, as defined by the State.

(5) The failure of an MCO, PIHP, or PAHP to act within the timeframes provided in § 438.408(b)(1) and (b)(2) regarding the standard disposition of grievances and standard disposition and resolution of appeals; or

(6) For a resident of a rural area with only one MCO, the denial of an enrollee's request to exercise his or her right, under § 438.52(b)(2)(ii), to obtain services outside the network.

Appeal means a review by a MCO, PIHP, or PAHP of an adverse benefit determination.

Grievance means an expression of dissatisfaction about any matter other than an adverse benefit determination. Grievances may include, but are not limited to, the quality of care or services provided, and aspects of interpersonal relationships such as rudeness of a provider or employee, or failure to respect the enrollee's rights regardless of whether remedial action is requested. Grievance includes an enrollee's right to dispute an extension of time proposed by the MCO, PIHP or PAHP to make an authorization decision.

Grievance system means the processes the MCO, PIHP, or PAHP implements to handle appeals of an adverse benefit determination and grievances, as well as the processes to collect and track information about them.

§ 438.402 General requirements.

(a) *The grievance system.* Each MCO, PIHP, and PAHP must have a grievance system in place for enrollees. Non-emergency medical transportation PAHPs, as defined in § 438.9, are not subject to subpart F.

(b) *Level of appeals.* Each MCO, PIHP and PAHP may have only one level of appeal for enrollees.

(c) *Filing requirements.* (1) *Authority to file.* (i) An enrollee may file a grievance and an appeal with the MCO, PIHP, or PAHP. An enrollee may request a State fair hearing after receiving notice under § 438.408 that the adverse benefit determination is upheld.

(ii) A provider, acting on behalf of the enrollee, may file an appeal. A provider may file a grievance or request a State fair hearing on behalf of an enrollee, if the State permits the provider to act as the enrollee's authorized representative in doing so.

(2) *Timing*—(i) *Grievance.* An enrollee may file a grievance with the MCO, PIHP, or PAHP at any time.

(ii) *Appeal.* Following receipt of a notification of an adverse benefit determination by an MCO, PIHP, or PAHP, an enrollee or the provider has 60 calendar days in which to file an appeal.

(3) *Procedures*—(i) *Grievance.* The enrollee may file a grievance either orally or in writing and, as determined by the State, either with the State or with the MCO, PIHP, or PAHP.

(ii) *Appeal.* The enrollee or a provider may file an appeal either orally or in writing. Further, unless the enrollee requests an expedited resolution, an oral appeal must be followed by a written, signed appeal.

§ 438.404 Timely and adequate notice of adverse benefit determination.

(a) *Notice.* The MCO, PIHP, or PAHP must give enrollees timely and adequate notice of adverse benefit determination in writing consistent with the requirements below and in § 438.10.

(b) *Content of notice.* The notice must explain the following:

(1) The adverse benefit determination the MCO, PIHP, or PAHP has made or intends to make.

(2) The reasons for the adverse benefit determination, including the right of the enrollee to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the enrollee's claim for benefits. Such information includes medical necessity criteria, and any processes, strategies, or evidentiary standards used in setting coverage limits.

(3) The enrollee's and the provider's right to file an appeal of the MCO's, PIHP's, or PAHP's adverse benefit determination.

(4) The procedures for exercising the rights specified in this paragraph (b).

(5) The circumstances under which an appeal process can be expedited and how to request it.

(6) The enrollee's right to have benefits continues pending resolution of

the appeal, how to request that benefits be continued, and the circumstances, consistent with state policy, under which the enrollee may be required to pay the costs of these services.

(c) *Timing of notice.* The MCO, PIHP, or PAHP must mail the notice within the following timeframes:

(1) For termination, suspension, or reduction of previously authorized Medicaid-covered services, within the timeframes specified in §§ 431.211, 431.213, and 431.214 of this chapter.

(2) For denial of payment, at the time of any action affecting the claim.

(3) For standard service authorization decisions that deny or limit services, within the timeframe specified in § 438.210(d)(1).

(4) If the MCO, PIHP, or PAHP meets the criteria set forth for extending the timeframe for standard service authorization decisions consistent with § 438.210(d)(1)(ii), it must—

(i) Give the enrollee written notice of the reason for the decision to extend the timeframe and inform the enrollee of the right to file a grievance if he or she disagrees with that decision; and

(ii) Issue and carry out its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(5) For service authorization decisions not reached within the timeframes specified in § 438.210(d) (which constitutes a denial and is thus an adverse benefit determination), on the date that the timeframes expire.

(6) For expedited service authorization decisions, within the timeframes specified in § 438.210(d)(2).

§ 438.406 Handling of grievances and appeals.

(a) *General requirements.* In handling grievances and appeals, each MCO, PIHP, and PAHP must give enrollees any reasonable assistance in completing forms and taking other procedural steps. This includes, but is not limited to, auxiliary aids and services upon request, such as providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability.

(b) *Special requirements.* An MCO's, PIHP's or PAHP's process for handling enrollee grievances and appeals of adverse benefit determinations must:

(1) Acknowledge receipt of each grievance and appeal.

(2) Ensure that the individuals who make decisions on grievances and appeals are individuals—

(i) Who were neither involved in any previous level of review or decision-making nor a subordinate of any such individual.

(ii) Who, if deciding any of the following, are health care professionals who have the appropriate clinical expertise, as determined by the State, in treating the enrollee's condition or disease.

(A) An appeal of a denial that is based on lack of medical necessity.

(B) A grievance regarding denial of expedited resolution of an appeal.

(C) A grievance or appeal that involves clinical issues.

(iii) That takes into account all comments, documents, records, and other information submitted by the enrollee or their representative without regard to whether such information was submitted or considered in the initial adverse benefit determination.

(3) Provide that oral inquiries seeking to appeal an adverse benefit determination are treated as appeals (to establish the earliest possible filing date for the appeal) and must be confirmed in writing, unless the enrollee or the provider requests expedited resolution.

(4) Provide the enrollee a reasonable opportunity, in person and in writing, to present evidence and testimony and make legal and factual arguments. The MCO, PIHP, or PAHP must inform the enrollee of the limited time available for this sufficiently in advance of the resolution timeframe for appeals as specified in § 438.408(b) and (c) in the case of expedited resolution.

(5) Provide the enrollee and his or her representative (free of charge and sufficiently in advance of the resolution timeframe for appeals as specified in § 438.408(b) and (c)) the enrollee's case file, including medical records, other documents and records, and any new or additional evidence considered, relied upon, or generated by the MCO, PIHP or PAHP (or at the direction of the MCO, PIHP or PAHP) in connection with the appeal of the adverse benefit determination.

(6) Include, as parties to the appeal—

(i) The enrollee and his or her representative; or

(ii) The legal representative of a deceased enrollee's estate.

§ 438.408 Resolution and notification: Grievances and appeals.

(a) *Basic rule.* Each MCO, PIHP, or PAHP must dispose of each grievance and resolve each appeal, and provide notice, as expeditiously as the enrollee's health condition requires, within State-established timeframes that may not exceed the timeframes specified in this section.

(b) *Specific timeframes.* (1) *Standard disposition of grievances.* For standard disposition of a grievance and notice to the affected parties, the timeframe is established by the State but may not exceed 90 calendar days from the day the MCO, PIHP, or PAHP receives the grievance.

(2) *Standard resolution of appeals.* For standard resolution of an appeal and notice to the affected parties, the State must establish a timeframe that is no longer than 30 calendar days from the day the MCO, PIHP, or PAHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

(3) *Expedited resolution of appeals.* For expedited resolution of an appeal and notice to affected parties, the State must establish a timeframe that is no longer than 72 hours after the MCO, PIHP, or PAHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

(c) *Extension of timeframes.* (1) The MCO, PIHP, or PAHP may extend the timeframes from paragraph (b) of this section by up to 14 calendar days if—

(i) The enrollee requests the extension; or

(ii) The MCO, PIHP, or PAHP shows (to the satisfaction of the State agency, upon its request) that there is need for additional information and how the delay is in the enrollee's interest.

(2) *Requirements following extension.* If the MCO, PIHP, or PAHP extends the timeframes not at the request of the enrollee, it must complete all of the following:

(i) Make reasonable efforts to give the enrollee prompt oral notice of the delay.

(ii) Within 2 calendar days give the enrollee written notice of the reason for the decision to extend the timeframe and inform the enrollee of the right to file a grievance if he or she disagrees with that decision.

(iii) Resolve the appeal as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(d) *Format of notice.* (1) *Grievances.* The State must establish the method that an MCO, PIHP, and PAHP will use to notify an enrollee of the disposition of a grievance and ensure that such methods meet, at a minimum, the standards described at § 438.10.

(2) *Appeals.* (i) For all appeals, the MCO, PIHP, or PAHP must provide written notice of disposition in a format and language that, at a minimum, meet the standards described at § 438.10.

(ii) For notice of an expedited resolution, the MCO, PIHP, or PAHP must also make reasonable efforts to provide oral notice.

(e) *Content of notice of appeal resolution.* The written notice of the resolution must include the following:

(1) The results of the resolution process and the date it was completed.

(2) For appeals not resolved wholly in favor of the enrollees—

(i) The right to request a State fair hearing, and how to do so.

(ii) The right to request and receive benefits while the hearing is pending, and how to make the request.

(iii) That the enrollee may, consistent with state policy, be held liable for the cost of those benefits if the hearing decision upholds the MCO's, PIHP's, or PAHP's adverse benefit determination.

(f) *Requirements for State fair hearings.* (1) *Availability.* An enrollee may request a State fair hearing only after receiving notice that the MCO, PIHP or PAHP is upholding the adverse benefit determination.

(2) The enrollee must request a State fair hearing no later than 120 calendar days from the date of the MCO's, PIHP's, or PAHP's notice of resolution.

(3) *Parties.* The parties to the State fair hearing include the MCO, PIHP, or PAHP as well as the enrollee and his or her representative or the representative of a deceased enrollee's estate.

§ 438.410 Expedited resolution of appeals.

(a) *General rule.* Each MCO, PIHP, and PAHP must establish and maintain an expedited review process for appeals, when the MCO, PIHP, or PAHP determines (for a request from the enrollee) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function.

(b) *Punitive action.* The MCO, PIHP, or PAHP must ensure that punitive action is not taken against a provider who requests an expedited resolution or supports an enrollee's appeal.

(c) *Action following denial of a request for expedited resolution.* If the MCO, PIHP, or PAHP denies a request for expedited resolution of an appeal, it must—

(1) Transfer the appeal to the timeframe for standard resolution in accordance with § 438.408(b)(2).

(2) Follow the requirements in § 438.408(c)(2).

§ 438.414 Information about the grievance system to providers and subcontractors.

The MCO, PIHP, or PAHP must provide information specified in § 438.10(g)(2)(xi) about the grievance system to all providers and subcontractors at the time they enter into a contract.

§ 438.416 Recordkeeping requirements.

(a) The State must require MCOs, PIHPs, and PAHPs to maintain records of grievances and appeals and must review the information as part of its ongoing monitoring procedures, as well as for updates and revisions to the State quality strategy.

(b) The record of each grievance or appeal must contain, at a minimum, all of the following information:

(1) A general description of the reason for the appeal or grievance.

(2) The date received.

(3) The date of each review or, if applicable, review meeting.

(4) Resolution at each level of the appeal or grievance, if applicable.

(5) Date of resolution at each level, if applicable.

(6) Name of the covered person for whom the appeal or grievance was filed.

(c) The record must be accurately maintained in a manner accessible to the state and available upon request to CMS.

§ 438.420 Continuation of benefits while the MCO, PIHP, or PAHP appeal and the State fair hearing are pending.

(a) *Definitions.* As used in this section—

Timely filing means filing on or before the later of the following:

(i) Within 10 calendar days of the MCO, PIHP, or PAHP mailing the notice of adverse benefit determination.

(ii) The intended effective date of the MCO's, PIHP's, or PAHP's proposed adverse benefit determination.

(b) *Continuation of benefits.* The MCO, PIHP, or PAHP must continue the enrollee's benefits if all of the following occur:

(1) The enrollee or the provider files the appeal timely.

(2) The appeal involves the termination, suspension, or reduction of a previously authorized course of treatment.

(3) The services were ordered by an authorized provider.

(4) The original period covered by the original authorization has not expired.

(5) The enrollee requests extension of benefits.

(c) *Duration of continued or reinstated benefits.* If, at the enrollee's request, the MCO, PIHP, or PAHP continues or reinstates the enrollee's benefits while the appeal is pending, the benefits must be continued until one of following occurs:

(1) The enrollee withdraws the appeal.

(2) Ten days pass after the MCO, PIHP, or PAHP mails the notice, providing the resolution of the appeal against the enrollee, unless the enrollee, within the 10-day timeframe, has requested a State fair hearing with continuation of benefits until a State fair hearing decision is reached.

(3) A State fair hearing office issues a hearing decision adverse to the enrollee.

(d) *Enrollee responsibility for services furnished while the appeal and state fair hearing is pending.* If the final resolution of the appeal is adverse to the enrollee, that is, upholds the MCO's, PIHP's, or PAHP's adverse benefit determination, the MCO, PIHP, or PAHP may recover the cost of the services furnished to the enrollee while the appeal and state fair hearing was pending, to the extent that they were furnished solely because of the requirements of this section, and in accordance with the policy set forth in § 431.230(b) of this chapter. The ability of the MCO, PIHP or PAHP to recoup the costs of services from the enrollee must be specified in the contract. Such practices must be consistently applied within the State under managed care and FFS delivery systems.

§ 438.424 Effectuation of reversed appeal resolutions.

(a) *Services not furnished while the appeal is pending.* If the MCO, PIHP, or PAHP, or the State fair hearing officer reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the MCO, PIHP, or PAHP must authorize or provide the disputed services promptly, and as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination.

(b) *Services furnished while the appeal is pending.* If the MCO, PIHP, or PAHP, or the State fair hearing officer reverses a decision to deny authorization of services, and the enrollee received the disputed services while the appeal was pending, the MCO, PIHP, or PAHP, or the State must pay for those services, in accordance with State policy and regulations.

Subpart G—[Reserved]

Subpart H—Additional Program Integrity Safeguards

§ 438.600 Statutory basis.

This subpart is based on the following statutory sections:

(a) Section 1128 of the Act provides for the exclusion of certain individuals and entities from participation in the Medicaid program.

(b) Section 1128J(d) of the Act requires that persons who have received an overpayment under Medicaid report and return the overpayment within 60

days after the date on which the overpayment was identified.

(c) Section 1902(a)(4) of the Act requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(d) Section 1902(a)(19) of the Act requires that the State plan provide the safeguards necessary to ensure that eligibility is determined and services are provided in a manner consistent with simplicity of administration and the best interests of the beneficiaries.

(e) Section 1902(a)(27) of the Act requires States to enroll persons or institutions that provide services under the State plan.

(f) Section 1902(a)(68) of the Act requires that any entity receiving annual payments under the State plan of at least $5,000,000 must establish certain minimum written policies relating to the Federal False Claims Act.

(g) Section 1902(a)(77) of the Act requires that States comply with provider and supplier screening, oversight, and reporting requirements described in section 1902(kk)(1) of the Act.

(h) Section 1902(a)(80) of the Act prohibits payments for items or services provided under the State plan or under a waiver to any financial institution or entity located outside of the United States.

(i) Section 1902(kk)(7) of the Act requires States to enroll physicians or other professionals that order or refer services under the State plan.

(j) Section 1903(i) of the Act prohibits FFP for amounts expended by MCOs or PCCMs for providers excluded by Medicare, Medicaid, or CHIP, except for emergency services.

(k) Section 1903(m) of the Act establishes conditions for payments to the State for contracts with MCOs.

(l) Section 1932(d)(1) of the Act prohibits MCOs and PCCMs from knowingly having certain types of relationships with individuals and entities debarred under Federal regulations from participating in specified activities, or with affiliates of those individuals.

§ 438.602 State responsibilities.

(a) *Monitoring contractor compliance.* Consistent with § 438.66, the State must monitor the MCO's, PIHP's, PAHP's, PCCM's or PCCM entity's compliance, as applicable, with § 438.604, § 438.606, § 438.608, § 438.610, § 438.230, and § 438.808.

(b) *Screening and enrollment and revalidation of providers.* The State must screen and enroll, and periodically revalidate, all network providers of MCOs, PIHPs, and PAHPs, in accordance with the requirements of part 455, subparts B and E of this chapter. This requirement extends to PCCMs and PCCM entities to the extent the primary care case manager is not otherwise enrolled with the State to provide services to FFS beneficiaries. This provision does not require the network provider to render services to FFS beneficiaries.

(c) *Ownership and control information.* The State must review the ownership and control disclosures submitted by the MCO, PIHP, PAHP, PCCM or PCCM entity, and any subcontractors, subject to the requirements in § 438.230, in accordance with subpart B of part 455 of this chapter.

(d) *Federal database checks.* Consistent with the requirements at § 455.436 of this chapter, the State must confirm the identity and determine the exclusion status of the MCO, PIHP, PAHP, PCCM or PCCM entity, any subcontractor, as well as any person with an ownership or control interest, or who is an agent or managing employee of the MCO, PIHP, PAHP, PCCM or PCCM entity through routine checks of Federal databases. This includes the Social Security Administration's Death Master File, the List of Excluded Individuals/Entities (LEIE), the System for Award Management (SAM), and any other databases as the State or Secretary may prescribe. These databases must be consulted upon contracting and no less frequently than monthly thereafter. If the state determines a match, it must promptly notify the MCO, PIHP, PAHP, PCCM, or PCCM entity and take action consistent with § 438.610(c).

(e) *Periodic audits.* The State must periodically, but no less frequently than once every 3 years, conduct, or contract for the conduct of, an independent audit of the accuracy, truthfulness, and completeness of the encounter and financial data submitted by, or on behalf of, each MCO, PIHP or PAHP.

(f) *Whistleblowers.* The State must receive and investigate information from whistleblowers relating to the integrity of the MCO, PIHP, PAHP, PCCM, or PCCM entity, subcontractors, or network providers receiving Federal funds under this part.

(g) *Transparency.* The State must post on its Web site or make available upon request the following documents and reports:

(1) The MCO, PIHP, PAHP, or PCCM entity contract.

(2) The data submitted under § 438.604.

(3) The results of any audits under paragraph (e) of this section.

(h) *Contracting integrity.* The State must have in place conflict of interest safeguards described in § 438.58 and must comply with the requirement described in section 1902(a)(4)(C) of the Act applicable to contracting officers, employees, or independent contractors.

(i) *Entities located outside of the U.S.* The State must ensure that the MCO, PIHP, PAHP, PCCM, or PCCM entity with which the State contracts under this part is not located outside of the United States and that no claims paid by an MCO, PIHP, or PAHP to a network provider, out-of-network provider, subcontractor or financial institution located outside of the U.S. are considered in the development of actuarially sound capitation rates.

§ 438.604 Data, information, and documentation that must be submitted.

(a) *Specified data, information, and documentation.* The State must require any MCO, PIHP, PAHP, PCCM or PCCM entity to submit to the State the following data:

(1) Encounter data in the form and manner described in § 438.818.

(2) Data on the basis of which the State certifies the actuarial soundness of capitation rates to an MCO, PIHP or PAHP under § 438.3, including base data described in § 438.5(c) that is generated by the MCO, PIHP or PAHP.

(3) Data on the basis of which the State determines the compliance of the MCO, PIHP, or PAHP with the medical loss ratio requirement described in § 438.8.

(4) Data on the basis of which the State determines that the MCO, PIHP or PAHP has made adequate provision against the risk of insolvency as required under § 438.116.

(5) Documentation described in § 438.207(b) on which the State bases its certification that the MCO, PIHP or PAHP has complied with the State's requirements for availability and accessibility of services, including the adequacy of the provider network, as set forth in § 438.206.

(6) Information on ownership and control described in § 455.104 of this chapter from MCOs, PIHPs, PAHPs, PCCMs, PCCM entities, and subcontractors as governed by § 438.230.

(7) The annual report of overpayment recoveries as required in § 438.608(d)(3).

(b) *Additional data, documentation, or information.* In addition to the data, documentation, or information specified in paragraph (a) of this section, an MCO, PIHP, PAHP, PCCM or PCCM entity must submit any other data, documentation, or information relating to the performance of the entity's

obligations under this part required by the State or the Secretary.

§ 438.606 Source, content, and timing of certification.

(a) *Source of certification.* For the data, documentation, or information specified in § 438.604, the State must require that the data, documentation or information the MCO, PIHP, PAHP, PCCM or PCCM entity submits to the State be certified by either the MCO's, PIHP's, PAHP's, PCCM's, or PCCM entity's Chief Executive Officer or Chief Financial Officer.

(b) *Content of certification.* The certification provided by the individual in paragraph (a) of this section must attest that the MCO, PIHP, PAHP, PCCM, or PCCM entity has conducted a reasonably diligent review of the data, documentation, and information specified in § 438.604(a) and (b), and that the data documentation, and information is accurate, complete, and truthful.

(c) *Timing of certification.* The State must require the MCO, PIHP, PAHP, PCCM. or PCCM entity to submit the certification concurrently with the submission of the data, documentation, or information required in § 438.604(a) and (b).

§ 438.608 Program integrity requirements under the contract.

(a) *Administrative and management arrangements or procedures to detect and prevent fraud, waste and abuse.* The State, through its contract with the MCO, PIHP or PAHP, must require that the MCO, PIHP, or PAHP, or subcontractor to the extent that the subcontractor is delegated responsibility by the MCO, PIHP, or PAHP for coverage of services and payment of claims under the contract between the State and the MCO, PIHP, or PAHP, implement and maintain arrangements or procedures that are designed to detect and prevent fraud, waste, and abuse. The arrangements or procedures must include the following:

(1) A compliance program that includes, at a minimum, all of the following elements:

(i) Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable requirements and standards under the contract, and all applicable Federal and State requirements.

(ii) The designation of a Compliance Officer who is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements of the contract and who reports directly to the Chief Executive Officer and the board of directors.

(iii) The establishment of a Regulatory Compliance Committee on the Board of Directors and at the senior management level charged with overseeing the organization's compliance program and its compliance with the requirements under the contract.

(iv) A system for training and education for the Compliance Officer, the organization's senior management, and the organization's employees for the Federal and State standards and requirements under the contract.

(v) Effective lines of communication between the compliance officer and the organization's employees.

(vi) Enforcement of standards through well-publicized disciplinary guidelines.

(vii) Establishment and implementation of procedures and a system with dedicated staff for routine internal monitoring and auditing of compliance risks, prompt response to compliance issues as they are raised, investigation of potential compliance problems as identified in the course of self-evaluation and audits, correction of such problems promptly and thoroughly (or coordination of suspected criminal acts with law enforcement agencies) to reduce the potential for recurrence, and ongoing compliance with the requirements under the contract.

(2) Provision for prompt reporting of all improper payments identified or recovered, specifying the improper payments due to potential fraud, to the State or law enforcement.

(3) Provision for prompt notification to the State when it receives information about changes in an enrollee's circumstances that may affect the enrollee's eligibility including all of the following:

(i) Changes in the enrollee's residence or notification of an enrollee's mail that is returned as undeliverable.

(ii) Changes in the enrollee's income.

(iii) The death of an enrollee.

(4) Provision for notification to the State when it receives information about a change in a provider's circumstances that may affect the provider's eligibility to participate in the managed care program, including the termination of the provider agreement with the MCO, PIHP or PAHP.

(5) Provision for a method to verify, by sampling or other methods, whether services that have been represented to have been delivered by network providers were received by enrollees and the application of such verification processes on a regular basis.

(6) In the case of MCOs, PIHPs, or PAHPs that receive annual payments under the contract of at least $5,000,000, written policies for all employees of the entity, and of any contractor or agent, providing detailed information about the False Claims Act and other Federal and State laws described in section 1902(a)(68) of the Act, including information about rights of employees to be protected as whistleblowers are in place.

(7) Provision for the prompt referral of any potential fraud, waste, or abuse that the MCO, PIHP, or PAHP identifies to the State Medicaid program integrity unit or any potential fraud directly to the State Medicaid Fraud Control Unit.

(8) Provision for the MCO's, PIHP's, or PAHP's suspension of payments to a network provider for which the State determines there is a credible allegation of fraud in accordance with § 455.23 of this chapter.

(b) *Provider screening and enrollment requirements.* The State, through its contracts with a MCO, PIHP, PAHP, PCCM, or PCCM entity must ensure that all network providers are enrolled with the State as Medicaid providers consistent with the provider disclosure, screening and enrollment requirements of part 455, subparts B and E of this chapter. This provision does not require the network provider to render services to FFS beneficiaries.

(c) *Disclosures.* The State must ensure, through its contracts, that each MCO, PIHP, PAHP, PCCM, PCCM entity, and any subcontractors:

(1) Provides written disclosure of any prohibited affiliation under § 438.610.

(2) Provides written disclosures of information on ownership and control required under § 455.104.

(3) Reports to the State within 60 calendar days when it has identified the capitation payments or other payments in excess of amounts specified in the contract.

(d) *Treatment of recoveries made by the MCO, PIHP or PAHP of overpayments to providers.* (1) Contracts with a MCO, PIHP, or PAHP must specify that the MCO, PIHP or PAHP retains the following:

(i) Payments made to a network provider that was otherwise excluded from participation in the Medicaid program, and subsequently recovered from that network provider, by an MCO, PIHP or PAHP.

(ii) Payments made to a network provider due to fraud, waste or abuse, and subsequently recovered from that network provider, by an MCO, PIHP or PAHP.

(2) Each MCO, PIHP, or PAHP requires and has a mechanism for a network provider to report to the MCO, PIHP or PAHP when it has received an overpayment, to return the overpayment

to the MCO, PIHP or PAHP within 60 calendar days after the date on which the overpayment was identified, and to notify the MCO, PIHP or PAHP in writing of the reason for the overpayment.

(3) Each MCO, PIHP, or PAHP must report annually to the State on their recoveries of overpayments.

(4) The State must use the results of the report in paragraph (d)(3) of this section for setting actuarially sound capitation rates for each MCO, PIHP, or PAHP consistent with the requirements in § 438.4.

(5) For purposes of paragraph (d) of this section, an overpayment is any payment made to a network provider by a MCO, PIHP, or PAHP to which the network provider is not entitled to under title XIX of the Act.

§ 438.610 Prohibited affiliations.

(a) An MCO, PIHP, PAHP, PCCM, or PCCM entity may not knowingly have a relationship of the type described in paragraph (c) of this section with the following:

(1) An individual or entity that is debarred, suspended, or otherwise excluded from participating in procurement activities under the Federal Acquisition Regulation or from participating in nonprocurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549.

(2) An individual or entity who is an affiliate, as defined in the Federal Acquisition Regulation, of a person described in paragraph (a)(1) of this section.

(b) An MCO, PIHP, PAHP, PCCM, or PCCM entity may not have a relationship with an individual or entity that is excluded from participation in any Federal health care program under section 1128 or 1128A of the Act.

(c) The relationships described in paragraph (a) of this section, are as follows:

(1) A director, officer, or partner of the MCO, PIHP, PAHP, PCCM. or PCCM entity.

(2) A subcontractor of the MCO, PIHP, PAHP, PCCM, or PCCM entity, as governed by § 438.230.

(3) A person with beneficial ownership of 5 percent or more of the MCO's, PIHP's, PAHP's, PCCM's, or PCCM entity's equity.

(4) A network provider or persons with an employment, consulting or other arrangement with the MCO, PIHP, PAHP, PCCM, or PCCM entity for the provision of items and services that are significant and material to the MCO's, PIHP's, PAHP's, PCCM's, or PCCM entity's obligations under its contract with the State.

(d) *Effect of noncompliance.* If a State finds that an MCO, PIHP, PAHP, PCCM, or PCCM entity is not in compliance with paragraphs (a) and (b) of this section, the State:

(1) Must notify the Secretary of the noncompliance.

(2) May continue an existing agreement with the MCO, PIHP, PAHP, PCCM, or PCCM entity unless the Secretary directs otherwise.

(3) May not renew or otherwise extend the duration of an existing agreement with the MCO, PIHP, PAHP, PCCM, or PCCM entity unless the Secretary provides to the State and to Congress a written statement describing compelling reasons that exist for renewing or extending the agreement despite the prohibited affiliations.

(4) Nothing in this section must be construed to limit or otherwise affect any remedies available to the U.S. under sections 1128, 1128A or 1128B of the Act.

(e) *Consultation with the Inspector General.* Any action by the Secretary described in paragraphs (d)(2) or (d)(3) of this section is taken in consultation with the Inspector General.

Subpart I—Sanctions

§ 438.700 Basis for imposition of sanctions.

(a) Each State that contracts with an MCO must, and each State that contracts with a PCCM or PCCM entity may, establish intermediate sanctions (which may include those specified in § 438.702) that it may impose if it makes any of the determinations specified in paragraphs (b) through (d) of this section. The State may base its determinations on findings from onsite surveys, enrollee or other complaints, financial status, or any other source.

(b) A State determines whether an MCO acts or fails to act as follows:

(1) Fails substantially to provide medically necessary services that the MCO is required to provide, under law or under its contract with the State, to an enrollee covered under the contract.

(2) Imposes on enrollees premiums or charges that are in excess of the premiums or charges permitted under the Medicaid program.

(3) Acts to discriminate among enrollees on the basis of their health status or need for health care services. This includes termination of enrollment or refusal to reenroll a beneficiary, except as permitted under the Medicaid program, or any practice that would reasonably be expected to discourage enrollment by beneficiaries whose medical condition or history indicates probable need for substantial future medical services.

(4) Misrepresents or falsifies information that it furnishes to CMS or to the State.

(5) Misrepresents or falsifies information that it furnishes to an enrollee, potential enrollee, or health care provider.

(6) Fails to comply with the requirements for physician incentive plans, as set forth (for Medicare) in §§ 422.208 and 422.210 of this chapter.

(c) A State determines whether an MCO, PCCM or PCCM entity has distributed directly, or indirectly through any agent or independent contractor, marketing materials that have not been approved by the State or that contain false or materially misleading information.

(d) A State determines whether—

(1) An MCO has violated any of the other requirements of sections 1903(m) or 1932 of the Act, or any implementing regulations.

(2) A PCCM or PCCM entity has violated any of the other applicable requirements of sections 1932 or 1905(t)(3) of the Act, or any implementing regulations.

(3) For any of the violations under paragraphs (d)(1) and (d)(2) of this section, only the sanctions specified in § 438.702, paragraphs (a)(3), (a)(4), and (a)(5) may be imposed.

§ 438.702 Types of intermediate sanctions.

(a) The types of intermediate sanctions that a State may impose under this subpart include the following:

(1) Civil money penalties in the amounts specified in § 438.704.

(2) Appointment of temporary management for an MCO as provided in § 438.706.

(3) Granting enrollees the right to terminate enrollment without cause and notifying the affected enrollees of their right to disenroll.

(4) Suspension of all new enrollment, including default enrollment, after the date the Secretary or the State notifies the MCO of a determination of a violation of any requirement under sections 1903(m) or 1932 of the Act.

(5) Suspension of payment for beneficiaries enrolled after the effective date of the sanction and until CMS or the State is satisfied that the reason for imposition of the sanction no longer exists and is not likely to recur.

(b) State agencies retain authority to impose additional sanctions under State statutes or State regulations that address areas of noncompliance specified in § 438.700, as well as additional areas of noncompliance. Nothing in this subpart

prevents State agencies from exercising that authority.

§ 438.704 Amounts of civil money penalties.

(a) *General rule.* If the State imposes civil monetary penalties as provided under § 438.702(a)(1), the maximum civil money penalty the State may impose varies depending on the nature of the MCO's, PCCM or PCCM entity's action or failure to act, as provided in this section.

(b) *Specific limits.* (1) The limit is $25,000 for each determination under § 438.700(b)(1), (b)(5), (b)(6), and (c).

(2) The limit is $100,000 for each determination under § 438.700(b)(3) or (b)(4).

(3) The limit is $15,000 for each beneficiary the State determines was not enrolled because of a discriminatory practice under § 438.700 (b)(3). (This is subject to the overall limit of $100,000 under paragraph (b)(2) of this section).

(c) *Specific amount.* For premiums or charges in excess of the amounts permitted under the Medicaid program, the maximum amount of the penalty is $25,000 or double the amount of the excess charges, whichever is greater. The State must deduct from the penalty the amount of overcharge and return it to the affected enrollees.

§ 438.706 Special rules for temporary management.

(a) *Optional imposition of sanction.* If the State imposes temporary management under § 438.702(a)(3), the State may do so only if it finds (through onsite surveys, enrollee or other complaints, financial status, or any other source) any of the following:

(1) There is continued egregious behavior by the MCO, including but not limited to behavior that is described in § 438.700, or that is contrary to any requirements of sections 1903(m) and 1932 of the Act.

(2) There is substantial risk to enrollees' health.

(3) The sanction is necessary to ensure the health of the MCO's enrollees—

(i) While improvements are made to remedy violations under § 438.700.

(ii) Until there is an orderly termination or reorganization of the MCO.

(b) *Required imposition of sanction.* The State must impose temporary management (regardless of any other sanction that may be imposed) if it finds that an MCO has repeatedly failed to meet substantive requirements in sections 1903(m) or 1932 of the Act, or this subpart. The State must also grant enrollees the right to terminate enrollment without cause, as described in § 438.702(a)(3), and must notify the affected enrollees of their right to terminate enrollment.

(c) *Hearing.* The State may not delay imposition of temporary management to provide a hearing before imposing this sanction.

(d) *Duration of sanction.* The State may not terminate temporary management until it determines that the MCO can ensure that the sanctioned behavior will not recur.

§ 438.708 Termination of an MCO, PCCM or PCCM entity contract.

A State has the authority to terminate an MCO, PCCM or PCCM entity contract and enroll that entity's enrollees in other MCOs, PCCMs or PCCM entities, or provide their Medicaid benefits through other options included in the State plan, if the State determines that the MCO, PCCM or PCCM entity has failed to do either of the following:

(a) Carry out the substantive terms of its contract.

(b) Meet applicable requirements in sections 1932, 1903(m), and 1905(t) of the Act.

§ 438.710 Notice of sanction and pre-termination hearing.

(a) *Notice of sanction.* Except as provided in § 438.706(c), before imposing any of the intermediate sanctions specified in this subpart, the State must give the affected entity timely written notice that explains the following:

(1) The basis and nature of the sanction.

(2) Any other appeal rights that the State elects to provide.

(b) *Pre-termination hearing.* (1) *General rule.* Before terminating an MCO, PCCM or PCCM entity contract under § 438.708, the State must provide the entity a pre-termination hearing.

(2) *Procedures.* The State must do all of the following:

(i) Give the MCO, PCCM or PCCM entity written notice of its intent to terminate, the reason for termination, and the time and place of the hearing.

(ii) After the hearing, give the entity written notice of the decision affirming or reversing the proposed termination of the contract and, for an affirming decision, the effective date of termination.

(iii) For an affirming decision, give enrollees of the MCO, PCCM or PCCM entity notice of the termination and information, consistent with § 438.10, on their options for receiving Medicaid services following the effective date of termination.

§ 438.722 Disenrollment during termination hearing process.

After a State notifies an MCO, PCCM or PCCM entity that it intends to terminate the contract, the State may do the following:

(a) Give the entity's enrollees written notice of the State's intent to terminate the contract.

(b) Allow enrollees to disenroll immediately without cause.

§ 438.724 Notice to CMS.

(a) The State must give CMS written notice whenever it imposes or lifts a sanction for one of the violations listed in § 438.700.

(b) The notice must adhere to all of the following requirements:

(1) Be given no later than 30 days after the State imposes or lifts a sanction.

(2) Specify the affected MCO, the kind of sanction, and the reason for the State's decision to impose or lift a sanction.

§ 438.726 State plan requirement.

(a) The State plan must include a plan to monitor for violations that involve the actions and failures to act specified in this part and to implement the provisions of this part.

(b) A contract with an MCO must provide that payments provided for under the contract will be denied for new enrollees when, and for so long as, payment for those enrollees is denied by CMS under § 438.730(e).

§ 438.730 Sanction by CMS: Special rules for MCOs.

(a) *Basis for sanction.* A State may recommend that CMS impose the denial of payment sanction specified in paragraph (e) of this section on an MCO with a contract under this part if the agency determines that the MCO acts or fails to act as specified in § 438.700(b)(1) through (b)(6).

(b) *Effect of an agency determination.* (1) The State's determination becomes CMS' determination for purposes of section 1903(m)(5)(A) of the Act unless CMS reverses or modifies it within 15 days.

(2) When the State decides to recommend imposing the sanction described in paragraph (e) of this section, this recommendation becomes CMS' decision, for purposes of section 1903(m)(5)(B)(ii) of the Act, unless CMS rejects this recommendation within 15 days.

(c) *Notice of sanction.* If the State's determination becomes CMS' determination under paragraph (b)(2) of this section, the State takes all of the following actions:

(1) Gives the MCO written notice of the nature and basis of the proposed sanction.

(2) Allows the MCO 15 days from the date it receives the notice to provide evidence that it has not acted or failed to act in the manner that is the basis for the recommended sanction.

(3) May extend the initial 15-day period for an additional 15 days if—

(i) The MCO submits a written request that includes a credible explanation of why it needs additional time.

(ii) The request is received by CMS before the end of the initial period.

(iii) CMS has not determined that the MCO's conduct poses a threat to an enrollee's health or safety.

(d) *Informal reconsideration.* (1) If the MCO submits a timely response to the notice of sanction, the State—

(i) Conducts an informal reconsideration that includes review of the evidence by a State agency official who did not participate in the original recommendation.

(ii) Gives the MCO a concise written decision setting forth the factual and legal basis for the decision.

(iii) Forwards the decision to CMS.

(2) The State's decision under paragraph (d)(1)(ii) of this section becomes CMS' decision unless CMS reverses or modifies the decision within 15 days from date of receipt by CMS.

(3) If CMS reverses or modifies the State decision, the agency sends the MCO a copy of CMS' decision.

(e) *Denial of payment.* (1) CMS, based upon the recommendation of the agency, may deny payment to the State for new enrollees of the MCO under section 1903(m)(5)(B)(ii) of the Act in the following situations:

(i) If a CMS determination that an MCO has acted or failed to act, as described in paragraphs (b)(1) through (b)(6) of § 438.700, is affirmed on review under paragraph (d) of this section.

(ii) If the CMS determination is not timely contested by the MCO under paragraph (c) of this section.

(2) Under § 438.726(b), CMS' denial of payment for new enrollees automatically results in a denial of agency payments to the MCO for the same enrollees. (A new enrollee is an enrollee that applies for enrollment after the effective date in paragraph (f)(1) of this section.)

(f) *Effective date of sanction.* (1) If the MCO does not seek reconsideration, a sanction is effective 15 days after the date the MCO is notified under paragraph (c) of this section of the decision to impose the sanction.

(2) If the MCO seeks reconsideration, the following rules apply:

(i) Except as specified in paragraph (d)(2) of this section, the sanction is effective on the date specified in CMS' reconsideration notice.

(ii) If CMS, in consultation with the State, determines that the MCO's conduct poses a serious threat to an enrollee's health or safety, the sanction may be made effective earlier than the date of the agency's reconsideration decision under paragraph (d)(1)(ii) of this section.

(g) *CMS' role.* (1) CMS retains the right to independently perform the functions assigned to the State under paragraphs (a) through (d) of this section.

(2) At the same time that the State sends notice to the MCO under paragraph (c)(1) of this section, CMS forwards a copy of the notice to the OIG.

(3) CMS conveys the determination described in paragraph (b) of this section to the OIG for consideration of possible imposition of civil money penalties under section 1903(m)(5)(A) of the Act and part 1003. In accordance with the provisions of part 1003, the OIG may impose civil money penalties on the MCO in addition to, or in place of, the sanctions that may be imposed under this section.

Subpart J—Conditions for Federal Financial Participation (FFP)

§ 438.802 Basic requirements.

FFP is available in expenditures for payments under an MCO contract only for the periods during which the contract—

(a) Meets the requirements of this part; and

(b) Is in effect.

§ 438.806 Prior approval.

(a) *Comprehensive risk contracts.* FFP is available under a comprehensive risk contract only if all of the following apply:

(1) CMS has confirmed that the contractor meets the definition of an MCO or is one of the entities described in paragraphs (b)(2) through (b)(5) of § 438.3.

(2) The contract meets all the requirements of section 1903(m)(2)(A) of the Act, the applicable requirements of section 1932 of the Act, and the provisions of this part.

(b) *MCO contracts.* Prior approval by CMS is a condition for FFP under any MCO contract that extends for less than one full year or that has a value equal to, or greater than, the following threshold amounts:

(1) For 1998, the threshold is $1,000,000.

(2) For subsequent years, the amount is increased by the percentage increase in the consumer price index for all urban consumers.

(c) FFP is not available in an MCO contract that does not have prior approval from CMS under paragraph (b) of this section.

§ 438.807 Deferral and/or disallowance of FFP for non-compliance with Federal requirements.

CMS may defer and/or disallow FFP under a contract subject to approval under this part, payment amounts associated with services under a MCO contract, in accordance with the requirements in § 430.40 and § 430.42 of this chapter, respectively, if the Administrator finds that—

(a) The contract, as submitted for approval or as administered by the State, is non-compliant with the requirements of section 1903(m)(2)(A) of the Act, the applicable requirements of section 1932 of the Act, or the provisions of this part for the service or services; or

(b) The final capitation rates as developed and described in the rate certification are noncompliant with the requirements in §§ 438.4 through 438.7 for the service or services.

§ 438.808 Exclusion of entities.

(a) *General rule.* FFP is available in payments under MCO contracts or PIHP, PAHP, PCCM, or PCCM entity contracts under a section1915(b)(1) of the Act waiver only if the State excludes from the contracts any entities described in paragraph (b) of this section.

(b) *Entities that must be excluded.* (1) An entity that could be excluded under section 1128(b)(8) of the Act as being controlled by a sanctioned individual.

(2) An entity that has a substantial contractual relationship as defined in § 431.55(h)(3) of this chapter, either directly or indirectly, with an individual convicted of certain crimes as described in section 1128(b)(8)(B) of the Act or an individual described in § 438.610(a).

(3) An entity that employs or contracts, directly or indirectly, for the furnishing of health care, utilization review, medical social work, or administrative services, with one of the following:

(i) Any individual or entity described in § 438.610(a).

(ii) Any individual or entity that would provide those services through an individual or entity described in § 438.610(a).

§ 438.810 Expenditures for enrollment broker services.

(a) *Definitions.* As used in this section—

Enrollment activities means activities such as distributing, collecting, and processing enrollment materials and

taking enrollments by phone, in person, or through electronic methods of communication.

Enrollment broker means an individual or entity that performs choice counseling or enrollment activities, or both.

Enrollment services means choice counseling, or enrollment activities, or both.

(b) *Conditions that enrollment brokers must meet.* State expenditures for the use of enrollment brokers are considered necessary for the proper and efficient operation of the State plan and thus eligible for FFP only if the broker and its subcontractors meet the following conditions:

(1) *Independence.* The broker and its subcontractors are independent of any MCO, PIHP, PAHP, PCCM, PCCM entity or other health care provider in the State in which they provide enrollment services. A broker or subcontractor is not considered ''independent'' if it—

(i) Is an MCO, PIHP, PAHP, PCCM, PCCM entity or other health care provider in the State;

(ii) Is owned or controlled by an MCO, PIHP, PAHP, PCCM, PCCM entity or other health care provider in the State; or

(iii) Owns or controls an MCO, PIHP, PAHP, PCCM, PCCM entity or other health care provider in the State.

(2) *Freedom from conflict of interest.* The broker and its subcontractor are free from conflict of interest. A broker or subcontractor is not considered free from conflict of interest if any person who is the owner, employee, or consultant of the broker or subcontractor or has any contract with them—

(i) Has any direct or indirect financial interest in any entity or health care provider that furnishes services in the State in which the broker or subcontractor provides enrollment services;

(ii) Has been excluded from participation under Title XVIII or XIX of the Act;

(iii) Has been debarred by any Federal agency; or

(iv) Has been, or is now, subject to civil money penalties under the Act.

(3) *Approval.* The initial contract or memorandum of agreement (MOA) for services performed by the broker has been reviewed and approved by CMS.

§ 438.812 Costs under risk and nonrisk contracts.

(a) Under a risk contract, the total amount the State agency pays for carrying out the contract provisions is a medical assistance cost.

(b) Under a nonrisk contract—

(1) The amount the State agency pays for the furnishing of medical services to eligible beneficiaries is a medical assistance cost; and

(2) The amount the State agency pays for the contractor's performance of other functions is an administrative cost.

§ 438.816 Expenditures for independent consumer support services for enrollees using LTSS.

State expenditures for the person or entity providing the services outlined in § 438.71(e) are considered necessary for the proper and efficient operation of the State plan and thus eligible for FFP only if all of the following conditions are met:

(a) Costs must be supported by an allocation methodology that appears in the State's approved Public Assistance Cost Allocation Plan in § 433.34 of this chapter.

(b) The costs do not duplicate payment for activities that are already being offered or should be provided by other entities or paid by other programs.

(c) The person or entity providing the services must meet the requirements in § 438.810(b)(1) and (2).

(d) The initial contract or MOA for services performed has been reviewed and approved by CMS.

§ 438.818 Enrollee encounter data.

(a) FFP is available for expenditures under an MCO, PIHP, or PAHP contract only if the State meets the following conditions for providing sufficient and timely enrollee encounter data to CMS:

(1) Enrollee encounter data reports must comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) security and privacy standards and be submitted in the format required by the Medicaid Statistical Information System or format required by any successor system to the Medicaid Statistical Information System.

(2) States must ensure that enrollee encounter data is validated for accuracy and completeness before each data submission. States may use the external quality review activity required in § 438.358 for the validation of encounter data to meet this requirement.

(3) States must cooperate with CMS to fully comply with all encounter data reporting requirements of the Medicaid Statistical Information System or any successor system.

(b) CMS will assess a State's submission to determine if it complies with current criteria for accuracy and completeness.

(c) If, after being notified of compliance issues under paragraph (b) of this section the State is unable to make a data submission compliant, CMS will take appropriate steps to defer and/or disallow FFP on all or part of an MCO, PIHP, or PAHP contract in a manner based on the enrollee and specific service type of the noncompliant data.

(d) States must, within 90 days of the effective date of this requirement, submit to CMS a detailed plan of their procedures and processes to ensure that complete and accurate enrollee encounter data are being submitted timely.

Subpart K—[Reserved]

PART 440—SERVICES: GENERAL PROVISIONS

■ 9. The authority citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

■ 10. Section 440.262 is added to read as follows:

§ 440.262 Access and cultural considerations.

The State must have methods to promote access and delivery of services in a culturally competent manner to all beneficiaries, including those with limited English proficiency, diverse cultural and ethnic backgrounds, disabilities, and regardless of gender, sexual orientation or gender identity. These methods must ensure that beneficiaries have access to covered services that are delivered in a manner that meet their unique needs.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 11. The authority citation for part 457 continues to read as follows:

Authority: Section 1102 of the Social Security Act (42 U.S.C. 1302).

■ 12. Section 457.10 is amended by revising the definition of ''fee-for-service entity'' and adding the definitions of ''actuarially sound principles'', ''comprehensive risk contract'', ''external quality review'', ''external quality review organization'', ''managed care organization'', ''prepaid ambulatory health plan'', ''prepaid inpatient health plan'', ''primary care case management'', ''primary care case management entity'', ''primary care case manager'', and ''risk contract'' in alphabetical order to read as follows:

§ 457.10 Definitions and use of terms.

* * * * *

Actuarially sound principles means generally accepted actuarial principles and practices that are applied to determine aggregate utilization patterns,

are appropriate for the population and services to be covered, and have been certified by actuaries who meet the qualification standards established by the Actuarial Standards Board.

* * * * *

Comprehensive risk contract means a risk contract between the State and an MCO that covers comprehensive services, that is, inpatient hospital services and any of the following services, or any three or more of the following services:

(1) Outpatient hospital services.

(2) Rural health clinic services.

(3) FQHC services.

(4) Other laboratory and X-ray services.

(5) Nursing facility (NF) services.

(6) Early and periodic screening, diagnostic, and treatment (EPSDT) services.

(7) Family planning services.

(8) Physician services.

(9) Home health services.

* * * * *

External quality review (EQR) means the analysis and evaluation by an EQRO, of aggregated information on quality, timeliness, and access to the health care services that an MCO, PIHP, or PAHP, or their contractors furnish to CHIP beneficiaries.

External quality review organization (EQRO) means an organization that meets the competence and independence requirements set forth in § 438.354 of this chapter, and holds a contract with a State to perform external quality review, other EQR-related activities as set forth in § 438.358 of this chapter, or both.

* * * * *

Fee-for-service entity means any individual or entity that furnishes services under the program on a fee-for-service basis, including health insurance services.

* * * * *

Managed care organization (MCO) means an entity that has, or is seeking to qualify for, a comprehensive risk contract under this part, and that is—

(1) A Federally qualified HMO that meets the advance directives requirements of subpart I of part 489 of this chapter; or

(2) Any public or private entity that meets the advance directives requirements and is determined to also meet the following conditions:

(i) Makes the services it provides to its CHIP enrollees as accessible (in terms of timeliness, amount, duration, and scope) as those services are to other CHIP beneficiaries within the area served by the entity.

(ii) Meets the solvency standards of § 438.116 of this chapter.

* * * * *

Prepaid ambulatory health plan (PAHP) means an entity that—

(1) Provides services to enrollees under contract with the State, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates.

(2) Does not provide or arrange for, and is not otherwise responsible for the provision of any inpatient hospital or institutional services for its enrollees.

(3) Does not have a comprehensive risk contract.

Prepaid inpatient health plan (PIHP) means an entity that—

(1) Provides services to enrollees under contract with the State, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates.

(2) Provides, arranges for, or otherwise has responsibility for the provision of any inpatient hospital or institutional services for its enrollees.

(3) Does not have a comprehensive risk contract.

* * * * *

Primary care case management means a system under which:

(1) A PCCM contracts with the State to furnish case management services (which include the location, coordination and monitoring of primary health care services) to CHIP beneficiaries; or

(2) A PCCM entity contracts with the State to provide a defined set of functions to CHIP beneficiaries.

Primary care case management entity (PCCM entity) means an organization that provides any of the following functions, in addition to primary care case management services, for the State:

(1) Provision of intensive telephonic or face-to-face case management, including operation of a nurse triage advice line.

(2) Development of enrollee care plans.

(3) Execution of contracts with and/or oversight responsibilities for the activities of fee-for-service providers in the fee-for-service program.

(4) Provision of payments to fee-for-service providers on behalf of the State.

(5) Provision of enrollee outreach and education activities.

(6) Operation of a customer service call center.

(7) Review of provider claims, utilization and practice patterns to conduct provider profiling and/or practice improvement.

(8) Implementation of quality improvement activities including administering enrollee satisfaction surveys or collecting data necessary for performance measurement of providers.

(9) Coordination with behavioral health systems/providers.

(10) Coordination with long-term services and supports systems/providers.

Primary care case manager (PCCM) means a physician, a physician group practice or, at State option, any of the following in addition to primary care case management services:

(1) A physician assistant.

(2) A nurse practitioner.

(3) A certified nurse-midwife.

* * * * *

Risk contract means a contract under which the contractor—

(1) Assumes risk for the cost of the services covered under the contract.

(2) Incurs loss if the cost of furnishing the services exceeds the payments under the contract.

* * * * *

■ 13. Section 457.204 is amended by revising paragraph (a) to read as follows:

§ 457.204 Withholding of payment for failure to comply with Federal requirements.

(a) *Basis for withholding.* CMS withholds payments to the State, in whole or in part, only if, after giving the State notice, a reasonable opportunity for correction, and an opportunity for a hearing, the Administrator finds—

(1) That the State plan is in substantial noncompliance with the requirements of title XXI of the Act or the regulations in this part. Substantial non-compliance includes, but is not limited to, failure to comply with requirements that significantly affect federal or state oversight or state reporting; or

(2) That the State is conducting its program in substantial noncompliance with either the State plan or the requirements of title XXI of the Act or the regulations in this part. Substantial non-compliance includes, but is not limited to, failure to comply with requirements that significantly affect federal or state oversight or state reporting. (Hearings are generally not called until a reasonable effort has been made to resolve the issues through conferences and discussions. These efforts may be continued even if a date and place have been set for the hearing.)

* * * * *

■ 14. Section 457.700 is amended by redesignating paragraphs (a)(1) and (a)(2) as paragraphs (a)(3) and (a)(4), and adding new paragraphs (a)(1) and (a)(2) to read as follows:

§ 457.700 Basis, scope, and applicability.

(a) * * *

(1) Section 2101(a) of the Act, which provides that the purpose of title XXI is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner; and

(2) Section 2103(f)(3) of the Act, which required compliance with managed care requirements, including quality assurance standards; and

* * * * *

■ 15. Section 457.760 is added to subpart G to read as follows:

§ 457.760 CHIP component of the State comprehensive quality Strategy.

(a) *General rule.* As a component of the State comprehensive quality strategy required under part 431, subpart I of this chapter, each state must address how it will assess and improve the quality of health care and services furnished to all CHIP enrollees.

(b) Under the CHIP component of the State comprehensive quality strategy, the State must:

(1) Address all elements set forth in § 431.502 of this chapter; and

(2) Follow the development, evaluation, and revision requirements as provided in § 431.504 of this chapter.

(c) Each State contracting with an MCO, PIHP, or PAHP as defined in § 457.10 of this chapter must also address, within the comprehensive quality strategy in paragraph (a), the requirements described in § 457.1240 of this chapter.

§ 457.902 [Removed]

■ 16. Section 457.902 is removed.

■ 17. Section 457.940 is revised to read as follows:

§ 457.940 Procurement standards.

(a) A State must submit to CMS a written assurance that title XXI services will be provided in an effective and efficient manner. The State must submit the assurance—

(1) With the initial State plan; or

(2) For States with approved plans, with the first request to amend the approved plan.

(b) A State must provide for free and open competition, to the maximum extent practical, in the bidding of all procurement contracts for coverage or other services in accordance with the procurement requirements of 45 CFR 74.43 or 45 CFR 92.36, as applicable.

(c) All contracts under this part must include provisions that define a sound and complete procurement contract, as required by 45 CFR part 74 or 45 CFR part 92, as applicable.

■ 18. Section 457.950 is amended by revising paragraph (a) to read as follows:

§ 457.950 Contract and payment requirements including certification of payment-related information.

(a) *MCOs, PAHPs, PIHPs, PCCMs, and PCCM entities.* The contract requirements for MCOs, PAHPs, PIHPs, PCCMs, and PCCM entities are provided in § 457.1201.

* * * * *

■ 19. Subpart L is added to part 457 to read as follows:

Subpart L—Managed Care

Sec.

Subpart L—Managed Care

GENERAL PROVISIONS

§ 457.1200 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart implements the following sections of the Act:

(1) Section 2101(a), which provides that the purpose of Title XXI is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner.

(2) Section 2103(f)(3) and 2107(e)(1)(M) of the Act, which apply certain provisions of Title XIX related to Medicaid managed care to CHIP.

(3) Sections 2107(b) and 2107(e)(2) of the Act, which relate to program integrity.

(b) *Scope.* This subpart sets forth requirements for the provision of services through managed care organizations, prepaid ambulatory health plans, prepaid inpatient health plans, and primary care case management entities, as defined in § 457.10.

(c) *Applicability.* The requirements of this subpart apply to child health assistance provided under a separate child health program operating a managed care delivery system. Regulations relating to managed care that are applicable to a Medicaid expansion program are found at part 438 of this chapter.

§ 457.1201 Standard contract requirements.

(a) *CMS review.* The State must submit all MCO, PAHP, PIHP, PCCM, and PCCM entity contracts for review in accordance with standards specified by the Secretary.

(b) *Entities eligible for comprehensive risk contracts.* The State may enter into a comprehensive risk contract only with the following:

(1) An MCO.

(2) The entities identified in section 1903(m)(2)(B)(i), (ii), and (iii) of the Act.

(3) Community, Migrant, and Appalachian Health Centers identified in section 1903(m)(2)(G) of the Act. Unless they qualify for a total exemption under section 1903(m)(2)(B) of the Act, these entities are subject to the regulations governing MCOs under this part.

(c) *Payment.* The final contract rates per contracted MCO, PIHP, or PAHP must be specifically identified in the applicable contract submitted for CMS review. The final contract rates must be based only upon services covered under the State plan and additional services deemed by the State to be necessary to comply with the Mental Health Parity and Addiction Equity Act, follow the requirements in § 457.1203 and represent a payment amount that is adequate to allow the MCO, PIHP or PAHP to efficiently deliver high quality services to CHIP-eligible individuals in a manner compliant with contractual requirements.

(d) *Enrollment discrimination prohibited.* Contracts with MCOs, PAHPs, PIHPs, PCCMs and PCCM entities must provide as follows:

(1) The MCO, PAHP, PIHP, PCCM or PCCM entity accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by the Regional Administrator), up to the limits set under the contract.

(2) The MCO, PAHP, PIHP, PCCM or PCCM entity will not, on the basis of health status or need for health care services, discriminate against individuals eligible to enroll.

(3) The MCO, PAHP, PIHP, PCCM or PCCM entity will not discriminate against individuals eligible to enroll on the basis of race, color, national origin, sex, sexual orientation, gender identity, or disability, and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin, sex, sexual orientation, gender identity, or disability.

(e) *Compliance with applicable laws and conflict of interest safeguards.* All contracts with MCOs, PAHPs, PIHPs, PCCMs or PCCM entities must meet the following provisions:

(1) Comply with all applicable Federal and State laws and regulations including Title VI of the Civil Rights Act of 1964; Title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990 as amended; and section 1557 of the Patient Protection and Affordable Care Act.

(2) Comply with the conflict of interest safeguards described in § 457.1214.

(f) *Inspection and audit of records and access to facilities.* Risk contracts must provide that the State, CMS, and the Office of the Inspector General may inspect and audit any records or documents of the MCO, PAHP, PIHP, PCCM or PCCM entity or its subcontractors, and may inspect the premises, physical facilities, and equipment related to its CHIP enrollees.

(g) *Physician incentive plans.* (1) MCO, PAHP, and PIHP contracts must provide for compliance with the requirements set forth in §§ 422.208 and 422.210 of this chapter.

(2) In applying the provisions of §§ 422.208 and 422.210 of this chapter, references to ''MA organization,'' ''CMS,'' and ''Medicare beneficiaries'' must be read as references to ''MCO, PAHP, or PIHP,'' ''State,'' and ''CHIP beneficiaries,'' respectively.

(h) *Subcontracts.* All subcontracts must fulfill the requirements of this part for the service or activity delegated under the subcontract in accordance with § 457.1233(b).

(i) *Choice of health professional.* The contract must allow each enrollee to choose his or her health professional to the extent possible and appropriate.

(j) *Audited financial reports.* The contract must require MCOs, PAHPs, and PIHPs to submit audited financial reports on an annual basis. The audit must be conducted in accordance with generally accepted accounting principles and generally accepted auditing standards.

(k) *[Reserved]*

(l) *Additional rules for contracts with PCCMs.* A PCCM contract must meet the following requirements:

(1) Provide for reasonable and adequate hours of operation, including 24-hour availability of information, referral, and treatment for emergency medical conditions.

(2) Restrict enrollment to beneficiaries who reside sufficiently near one of the PCCM's delivery sites to reach that site within a reasonable time using available and affordable modes of transportation.

(3) Provide for arrangements with, or referrals to, sufficient numbers of physicians and other practitioners to ensure that services under the contract can be furnished to enrollees promptly and without compromise to quality of care.

(m) *Additional rules for contracts with PCCM entities.* In addition to the requirements in paragraph (l) of this section, the State must submit PCCM entity contracts to CMS for review to ensure compliance with the provisions of paragraph (l) of this section; § 457.1206; and if the State's contract with the PCCM entity provides for shared savings, incentive payments, or other financial reward for improved quality outcomes, § 457.1240(b), § 457.1240(e) and 457.1240(f) if the State's contract with the PCCM entity provides for shared savings, incentive payments or other financial reward for improved quality outcomes.

(n) *Attestations.* Contracts with MCO, PAHP, PIHP, PCCM or PCCM entities must include an attestation to the accuracy, completeness, and truthfulness of claims and payment data, under penalty of perjury.

(o) *Guarantee not to avoid costs.* Contracts with MCO, PAHP, PIHP, PCCM or PCCM entities must include a guarantee that the MCO, PAHP, PIHP, PCCM or PCCM entity will not avoid costs for services covered in its contract by referring enrollees to publicly supported health care resources.

(p) *Recordkeeping requirements.* MCOs, PIHPs, and PAHPs, must retain, and require subcontractors to retain, as applicable, the following information: enrollee grievance and appeal records in § 457.1260, MLR reports in § 457.1205, and the data, information, and documentation specified in § 457.1270 for a period of no less than 6 years.

§ 457.1203 Rate development standards.

(a) A state must use payment rates based on public or private payment rates for comparable services for comparable populations, consistent with actuarially sound principles as defined at § 457.10.

(b) A State may establish higher rates than permitted under paragraph (a) of this section if such rates are necessary to ensure sufficient provider participation, provider access, or to enroll providers who demonstrate exceptional efficiency or quality in the provision of services.

(c) The rates must be developed in such a way that the MCO, PIHP, or PAHP would reasonably achieve a medical loss ratio standard, as calculated under § 438.8 of this chapter, of at least 85 percent for the rate year. In addition, the rates must be developed in such a way to achieve a medical loss ratio standard, as calculated under § 438.8, that provides for reasonable administrative costs.

(d) The State must provide to CMS, if requested, a description of the manner in which rates were developed in accordance with the requirements of paragraphs (a), (b), or (c) of this section.

§ 457.1205 Medical loss ratio.

(a) The state must comply with the requirements related to medical loss ratios as provided in § 438.74 of this chapter, except that the description of the reports received from the MCOs, PIHPs and PAHPs pursuant to § 438.8(k) will not be submitted with the actuarial certification described in § 438.7.

(b) The state must ensure, through its contracts, that each MCO, PIHP, and PAHP complies with the requirements § 438.8 of this chapter.

§ 457.1206 Non-emergency medical transportation PAHPs.

(a) For purposes of this section Non-Emergency Medical Transportation (NEMT) PAHP means an entity that provides only NEMT services to enrollees under contract with the State, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates.

(b) Unless listed in this paragraph, a requirement of this part does not apply

to NEMT PAHPs, NEMT PAHP contracts, or States in connection with a NEMT PAHP. The following requirements and options apply to NEMT PAHPs, NEMT PAHP contracts, and States in connection with NEMT PAHPs, to the same extent that they apply to PAHPs, PAHP contracts, and States in connection with PAHPs.

(1) All contract provisions in § 457.1202 except requirements for:

(i) Physician Incentive plans;

(ii) Audited Financial Reports; and

(iii) MHPAEA.

(2) The rate development standards in § 457.1203.

(3) The information requirements in § 457.1207.

(4) The provision against provider discrimination in § 457.1208.

(5) The State responsibility provisions in §§ 457.1212, 457.1214, and 438.62(a) of this chapter, as cross referenced by § 457.1216.

(6) The provisions on enrollee rights and protections in §§ 457.1220, 457.1222, 457.1224, and 457.1226.

(7) The PAHP Standards in § 438.206(b)(1) of this chapter, as cross-referenced by §§ 457.1230(a); 457.1230(d); and 457.1233(a) through (c).

(8) An enrollee's right to a State review under subpart K of this chapter.

(9) Prohibitions against affiliations with individuals debarred or excluded by Federal agencies in § 457.1285.

§ 457.1207 Information requirements.

The State must provide, or ensure its contracted MCO, PAHP, PIHP, PCCM and PCCM entities provide all enrollment notices, informational materials, and instructional materials related to enrollees and potential enrollees as provided in § 438.10 of this chapter.

§ 457.1208 Requirements that apply to MCO, PIHP, PAHP, PCCM, and PCCM entity contracts involving Indians, Indian health care provider (IHCP), and Indian managed care entities (IMCE).

The State must follow, and ensure through its contracts, that each MCO, PIHP, PAHP, PCCM, and PCCM entity follows, the requirements related to Indians, IHCPs, and IMCEs as provided in § 438.14 of this chapter.

STATE RESPONSIBILITIES

§ 457.1210 Managed care enrollment.

(a) If a state uses a default enrollment process to assign beneficiaries to a MCO, PIHP, PAHP, PCCM, or PCCM entity, the process must:

(1) Assign beneficiaries to a qualified MCO, PIHP, PAHP, PCCM or PCCM entity. To be a qualified, the MCO, PIHP, PAHP, PCCM or PCCM entity must:

(i) Not be subject to the intermediate sanction described in § 438.702(a)(4) of this chapter.

(ii) Have capacity to enroll beneficiaries.

(2) Seek to preserve existing provider-beneficiary relationships and relationships with providers that have traditionally served CHIP beneficiaries.

(i) An ''existing provider-beneficiary relationship'' is one in which the provider was the main source of CHIP services for the beneficiary during the previous year. This may be established through State records of previous managed care enrollment or fee-for-service experience, encounter data, or through contact with the beneficiary.

(ii) A provider is considered to have ''traditionally served'' CHIP beneficiaries if it has experience in serving the CHIP population.

(3) If the approach in paragraph (a)(2) of this section is not possible, the State must distribute the beneficiaries equitably among the MCOs, PIHPs, PAHPs, PCCMs and PCCM entities.

(i) The State may not arbitrarily exclude any MCO, PIHP, PAHP, PCCM or PCCM entity from being considered.

(ii) The State may consider additional criteria to conduct the default enrollment process, including the enrollment preferences of family members, previous plan assignment of the beneficiary, quality assurance and improvement performance, procurement evaluation elements, accessibility of provider offices for people with disabilities (when appropriate), and other reasonable criteria that support the objectives of the managed care program.

(4) The State must send a confirmation of the enrollee's managed care enrollment to the enrollee within 5 calendar days of the MCO, PIHP, PAHP, PCCM or PCCM entity enrollment being processed by the State. The confirmation must clearly explain the enrollee's right to disenroll within 90 days from the effective date of the enrollment.

(b) *Priority for enrollment.* The state must have an enrollment system under which beneficiaries already enrolled in an MCO, PIHP, PAHP, PCCM, or PCCM entity are given priority to continue that enrollment if the MCO, PIHP, PAHP, PCCM, or PCCM entity does not have the capacity to accept all those seeking enrollment under the program.

§ 457.1212 Disenrollment.

The State must follow and ensure, through its contracts, that each MCO, PAHP, PIHP, PCCM and PCCM entity follows, the disenrollment requirements as provided in § 438.56 of this chapter, except that references to fair hearings should be read to refer to reviews as described in subpart K of this chapter.

§ 457.1214 Conflict of interest safeguards.

The State must have in effect safeguards against conflict of interest as provided in § 438.58 of this chapter.

§ 457.1216 Continued services to enrollees.

The State must follow the requirements related to continued services to enrollees as provided in § 438.62 of this chapter.

§ 457.1218 Network adequacy standards.

The State must develop network adequacy standards as provided in § 438.68 of this chapter, and, ensure through its contracts, that each MCO, PAHP, and PIHP meets such standards. In addition to developing standards provided in § 438.68 of this chapter, the state must develop time and distance standards for dental providers and pediatric specialists, if covered under the contracts.

ENROLLEE RIGHTS AND PROTECTIONS

§ 457.1220 Enrollee rights.

The State must ensure, through its contracts, that each MCO, PIHP, PAHP, PCCM, and PCCM entity follow the enrollee rights requirements as provided in § 438.100 of this chapter.

§ 457.1222 Provider-enrollee communication.

The State must ensure, through its contracts, that each MCO, PIHP, and PAHP protects communications between providers and enrollees as provided in § 438.102 of this chapter.

§ 457.1224 Marketing activities.

The State must ensure, through its contracts, that each MCO, PIHP, PAHP, PCCM, and PCCM entity follows the requirements related to marketing activities as provided in § 438.104 of this chapter.

§ 457.1226 Liability for payment.

The State must ensure, through its contracts, that enrollees of MCOs, PIHPs, and PAHPs are not held liable for services or debts of the MCO, PIHP, or PAHPs as provided in § 438.106 of this chapter.

§ 457.1228 Emergency and poststabilization services.

The State must ensure that emergency services, as defined in § 457.10, are available and accessible to enrollees as provided in § 438.114 of this chapter.

MCO, PIHP, AND PAHP STANDARDS

§ 457.1230 Access standards.

(a) *Availability of services.* The State must ensure that the services are available and accessible to enrollees as provided in § 438.206 of this chapter.

(b) *Assurances of adequate capacity and services.* The State must ensure, through its contracts, that each MCO, PIHP and PAHP has adequate capacity to serve the expected enrollment as provided in § 438.207 of this chapter.

(c) *Coordination and continuity of care.* The State must ensure, through its contracts, that each MCO, PIHP and PAHP complies with the coordination and continuity of care requirements as provided in § 438.208 of this chapter.

(d) *Coverage and authorization of services.* The State must ensure, through its contracts, that each MCO, PIHP or PAHP complies with the coverage and authorization of services requirements as provided in § 438.210 of this chapter, except:

(1) Section 438.210(a)(5) related to medically necessary services does not apply;

(2) Notice of adverse benefit determination must meet the requirements of § 457.1260;

(3) The time frames set forth in § 438.210(d) do not apply. For the timeframe for decisions, each MCO, PIHP, or PAHP contract must provide for the decisions and notices in accordance with § 457.1160.

§ 457.1233 Structure and operation standards.

(a) *Provider selection.* The State must ensure, through its contracts, that each MCO, PIHP or PAHP complies with the provider selection requirements as provided in § 438.214 of this chapter.

(b) *Subcontractual relationships and delegation.* The State must ensure, through its contracts, that each MCO, PIHP and PAHP complies with the subcontractual relationships and delegation requirements as provided in § 438.230 of this chapter.

(c) *Practice guidelines.* The state must ensure, through its contracts, that each MCO and, when applicable, each PIHP and PAHP, complies with the practice guidelines requirements as provided in § 438.236 of this chapter.

(d) *Health information systems.* The State must ensure, through its contracts, that each MCO, PIHP, and PAHP complies with the health information systems requirements as provided in § 438.242 of this chapter.

QUALITY MEASUREMENT AND IMPROVEMENT; EXTERNAL QUALITY REVIEW

§ 457.1240 Quality measurement and improvement.

(a) *Scope.* This section sets forth requirements related to quality assessment and performance improvement that each State contracting with an MCO, PIHP, or PAHP must meet.

(b) *Quality assessment and performance improvement program.* The State must require, through its contracts, that each MCO, PIHP, and PAHP must establish and implement an ongoing comprehensive quality assessment and performance improvement program for the services it furnishes to its enrollees as provided in § 438.330, except that the terms of § 438.330(d)(3) of this chapter (for dual eligibles) do not apply.

(c) *State review and approval of MCOs, PIHPS, and PAHPs.* The State must review and approve the performance of each MCO, PIHP, and PAHP in accordance with the requirements as set forth in § 438.332 of this chapter.

(d) *Managed Care quality rating system.* The State must collect data and apply the methodology established by CMS under the process described in § 438.330(a)(2) to determine a quality rating or ratings for each MCO, PIHP, and PAHP in accordance with the requirements set forth in § 438.334, except that the terms of 438.334(d) of this chapter (for dual eligible) do not apply.

(e) *Managed care elements of the State comprehensive quality strategy.* In addition to the requirements set forth in § 457.760, any State contracting with an MCO, PIHP, or PAHP must also address the managed care elements described in § 438.340 of this chapter.

§ 457.1250 External quality review.

(a) Each State that contracts with MCOs, PIHPs, or PAHPs must follow all applicable external quality review requirements as set forth in §§ 438.350, 438.352, 438.354, 438.356, 438.358, and 438.364 of this chapter.

(b) *Exceptions.* (1) The following provisions do not apply to the CHIP external quality review process for States contracting with MCOs, PIHPs, or PAHPs;

(i) Nonduplication of mandatory activities (as set forth in § 438.360 of this chapter.)

(ii) Exemption from external quality review (as set forth in § 438.362 of this chapter.)

(2) A State may amend an existing EQRO contract to include the performance of EQR-related activities and/or EQR in accordance with paragraph (a) of this section, provided that the existing contract meets the requirements in § 438.356 of this chapter.

GRIEVANCE SYSTEM

§ 457.1260 Grievance system.

The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the grievance and appeals requirements and procedures as provided in subpart F of part 438 of this chapter, except that the terms of § 438.420 do not apply and that references to fair hearings should be read to refer to reviews as described in subpart K of this chapter.

SANCTIONS

§ 457.1270 Sanctions.

The State must comply, and ensure that its contracted MCOs comply, with the sanctions requirements as provided in subpart I of part 438 of this chapter.

■ 20. Add a new undesignated center heading to subpart K after § 457.1190 to read as follows:

PROGRAM INTEGRITY

§ 457.955 [Redesignated as § 457.1280]

■ 21. Section 457.955 is redesignated as new § 457.1280 in subpart K.

■ 22. Newly redesignated § 457.1280 is amended by revising the section heading and paragraphs (a), (b)(1), (b)(2), (b)(3), and (d) to read as follows:

§ 457.1280 Conditions necessary to contract as an MCO, PAHP, or PIHP.

(a) The State must assure that any entity seeking to contract as an MCO, PAHP, or PIHP under a separate child health program has administrative and management arrangements or procedures designed to safeguard against fraud and abuse.

(b) * * *

(1) Enforce MCO, PAHP, and PIHP compliance with all applicable Federal and State statues, regulations, and standards.

(2) Prohibit MCOs, PAHPs, and PIHPs from conducting any unsolicited personal contact with a potential enrollee by an employee or agent of the MCO, PAHP, or PIHP for the purpose of influencing the individual to enroll with the entity.

(3) Include a mechanism for MCOs, PAHPs, and PIHPs to report to the State, to CMS, or to the Office of Inspector General (OIG) as appropriate, information on violations of law by subcontractors, providers, or enrollees

of an MCO, PAHP, or PIHP and other individuals.

* * * * *

(d) The State may inspect, evaluate, and audit MCOs, PIHPs, and PAHPs at any time, as necessary, in instances where the State determines that there is a reasonable possibility of fraudulent and abusive activity.

■ 23. Section 457.1285 is added to subpart K to read as follows:

§ 457.1285 Program integrity safeguards.

The state must comply with the program integrity safeguards as provided in subpart H of part 438, except that the terms of § 438.604(a)(2) of this chapter do not apply.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 24. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 495.332 [Amended]

■ 25. In § 495.332, amend paragraph (d)(2) by removing the reference ''§ 438.6(v)(5)(iii)'' and add in its place the reference ''§ 438.6(b)(2)''.

§ 495.366 [Amended]

■ 26. In § 495.366, amend paragraph (e)(7) by removing the reference ''§ 438.6(c)(5)(iii)'' and add in its place the reference ''§ 438.6(b)(2)''.

Dated: March 11, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: May 21, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015–12965 Filed 5–26–15; 4:15 pm]

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FEDERAL REGISTER PAGES AND DATE, JUNE

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Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

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When a date falls on a weekend or holiday, the next Federal business day is used. (See 1 CFR 18.17)

A new table will be published in the first issue of each month.

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June 25	Jul 10	Jul 16	Jul 27	Jul 30	Aug 10	Aug 24	Sep 23
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