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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 985

[Doc. No. AMS–FV–13–0087; FV14–985–1C IR]

Marketing Order Regulating the Handling of Spearmint Oil Produced in the Far West; Revision of the Salable Quantity and Allotment Percentage for Class 3 (Native) Spearmint Oil for the 2014–2015 Marketing Year

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim rule with request for comments.

SUMMARY: This interim rule implements a recommendation from the Spearmint Oil Administrative Committee (Committee) to further revise the quantity of Class 3 (Native) spearmint oil that handlers may purchase from, or handle on behalf of, producers during the 2014–2015 marketing year under the Far West spearmint oil marketing order (order). The salable quantity and allotment percentage for Native spearmint oil was initially established at 1,090,821 pounds and 46 percent, respectively, and was subsequently increased to 1,280,561 pounds and 54 percent in a separate rulemaking action. This rule further increases the Native spearmint oil salable quantity to 1,351,704 pounds and the allotment percentage to 57 percent for the 2014–2015 marketing year. The order regulates the handling of spearmint oil produced in the Far West and is locally administered by the Committee, which is comprised of spearmint oil producers operating within the order's area of production. The Committee recommended this rule for the purpose of maintaining orderly marketing conditions in the Far West spearmint oil market.

DATES: Effective March 30, 2015 and applicable to the 2014–2015 marketing year; comments received by May 29, 2015 will be considered prior to issuance of a final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or Internet: *http://www.regulations.gov.* All comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.regulations.gov.* All comments submitted in response to this rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the Internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Barry Broadbent, Senior Marketing Specialist, or Gary Olson, Regional Director, Northwest Marketing Field Office, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA; Telephone: (503) 326–2724, Fax: (503) 326–7440, or Email: *Barry.Broadbent@ams.usda.gov* or *GaryD.Olson@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.Smutny@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This interim rule is issued under Marketing Order No. 985 (7 CFR part 985), as amended, regulating the handling of spearmint oil produced in the Far West (Washington, Idaho, Oregon, and designated parts of Nevada and Utah), 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 rule in conformance with Executive Orders 12866, 13563, and 13175.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the provisions of the marketing order now in effect, salable quantities and allotment percentages may be established for classes of spearmint oil produced in the Far West. This rule increases the quantity of Native spearmint oil produced in the Far West that handlers may purchase from, or handle on behalf of, producers during the 2014–2015 marketing year, which began on June 1, 2014, and ends on May 31, 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 rule revises the quantity of Native spearmint oil that handlers may purchase from, or handle on behalf of, producers during the 2014–2015 marketing year under the Far West spearmint oil marketing order. Prior to this rule, the salable quantity and allotment percentage for Native spearmint oil was initially established at 1,090,821 pounds and 46 percent, respectively, in a final rule published May 8, 2014 (79 FR 26359). The salable quantity and allotment percentage was subsequently increased to 1,280,561 pounds and 54 percent in an interim rule published January 22, 2015 (80 FR 3142). This interim rule further increases the Native spearmint oil salable quantity from 1,280,561 pounds to 1,351,704 pounds and the allotment percentage from 54 percent to 57 percent. This action is anticipated to be

the last revision of the Native spearmint oil salable quantity and allotment percentage established under the order for the 2014–2015 marketing year.

Under the volume regulation provisions of the order, the Committee meets each year to adopt a marketing policy for the ensuing year. When the Committee's marketing policy considerations indicate a need for limiting the quantity of spearmint oil available to the market to establish or maintain orderly marketing conditions, the Committee submits a recommendation to the Secretary for volume regulation.

Volume regulation under the order is effectuated through the establishment of a salable quantity and allotment percentage applicable to each class of spearmint oil handled in the production area during a marketing year. The salable quantity is the total quantity of each class of oil that handlers may purchase from, or handle on behalf of, producers during a given marketing year. The allotment percentage for each class of oil is derived by dividing the salable quantity by the total industry allotment base for that same class of oil. The total industry allotment base is the aggregate of all allotment base held individually by producers. Producer allotment base is the quantity of each class of spearmint oil that the Committee has determined is representative of a producer's spearmint oil production. Each producer is allotted a pro rata share of the total salable quantity of each class of spearmint oil each marketing year. Each producer's annual allotment is determined by applying the allotment percentage to the producer's individual allotment base for each applicable class of spearmint oil.

The full Committee met on November 6, 2013, to consider its marketing policy for the 2014–2015 marketing year. At that meeting, the Committee determined that marketing conditions indicated a need for volume regulation of both classes of spearmint oil for the 2014–2015 marketing year. The Committee recommended salable quantities of 1,149,030 pounds and 1,090,821 pounds, and allotment percentages of 55 percent and 46 percent, respectively, for Scotch and Native spearmint oil. A proposed rule to that effect was published in the **Federal Register** on March 14, 2014 (79 FR 14441). Comments on the proposed rule were solicited from interested persons until March 31, 2014. No comments were received. Subsequently, a final rule establishing the salable quantities and allotment percentages for Scotch and Native spearmint oil for the 2014–2015 marketing year was published in the **Federal Register** on May 8, 2014 (79 FR 26359).

Pursuant to authority contained in §§ 985.50, 985.51, and 985.52 of the order, the full eight member Committee met again on September 11, 2014, to consider pertinent market information on the current supply, demand, and price of spearmint oil. After some deliberation, the Committee recommended increasing the 2014–2015 marketing year Scotch spearmint oil salable quantity from 1,149,030 pounds to 1,984,423 pounds and the allotment percentage from 55 percent to 95 percent. An interim rule to that effect was published in the **Federal Register** on October 31, 2014 (79 FR 64657).

The full Committee met again on November 5, 2014, for a regularly scheduled annual meeting to evaluate the current year's volume control regulation and to adopt a marketing policy for the 2015–2016 marketing year. After thorough discussion with regards to the current marketing conditions for Native spearmint oil, the Committee recommended revising the previously established 2014–2015 marketing year Native spearmint oil salable quantity and allotment percentage. Subsequently, in an interim rule published in the **Federal Register** on January 22, 2015 (80 FR 3142), the salable quantity for Native spearmint oil was increased from 1,090,821 pounds to 1,280,561 pounds and the allotment percentage was increased from 46 percent to 54 percent.

The full Committee met again on February 18, 2015, for a regularly scheduled meeting where it again evaluated the current year's volume control regulation. At the meeting, the Committee assessed the current market conditions for spearmint oil in relation to the revised salable quantities and allotment percentages established for the 2014–2015 marketing year. The Committee considered a number of factors, including the current and projected supply, estimated future demand, production costs, and producer prices for all classes of spearmint oil. The Committee determined that the recently revised salable quantity and allotment percentage in effect for Native spearmint oil for the 2014–2015 marketing year should be further increased to take into account the unanticipated rise in market demand for that class of spearmint oil.

Therefore, the Committee recommended increasing the Native spearmint oil salable quantity from 1,280,561 pounds to 1,351,704 pounds and the allotment percentage from 54 percent to 57 percent. The recommendation to increase the salable quantity and allotment percentage passed unanimously.

Thus, taking into consideration the following discussion, this rule makes additional amounts of Native spearmint oil available to the market by further increasing the salable quantity and allotment percentage previously established under the order for the 2014–2015 marketing year. This rule increases the Native spearmint oil salable quantity 71,143 pounds, to 1,351,704 pounds, and raises the allotment percentage 3 percent points, to 57 percent. Such additional oil will become available to the market by releasing Native spearmint oil held by producers in the reserve pool. As of May 31, 2014, the Committee records show that the reserve pool for Native spearmint oil contained 446,086 pounds of oil.

The increase in the salable quantity as a result of this rule represents an additional 71,143 pounds of Native spearmint oil being made available to the market. However, as some individual producers do not hold Native spearmint oil from previous year's production in the reserve pool, the Committee expects that only 48,769 pounds of additional Native spearmint oil will actually be made available to the spearmint oil market. The relatively high salable quantity resulting from this action, as compared to the actual quantity of spearmint oil that will be made available to the market, is necessary to ensure that a sufficient quantity of Native spearmint oil is available to fully supply the market. Producers that do not have additional Native spearmint oil in inventory (oil held in the reserve pool) will not be able to utilize the additional annual allotment issued to them as a result of this action and such additional annual allotment will go unused.

At the February meeting, the Committee staff reported that demand for Native spearmint oil continues to be greater than anticipated. Committee records indicate that 2014–2015 marketing year sales through the end of January 2015, the most recent full month recorded, are 148,325 pounds higher than for the same period in the 2013–2014 marketing year and 211,163 pounds higher than the average sales for the same period for the years 2009–2013. The Committee now estimates trade demand for Native spearmint oil for the 2014–2015 marketing year to be approximately 1,443,899 pounds, up from the 1,300,000 pounds initially estimated in the fall of 2013, and the 1,341,000 pounds estimated at the Committee's November 2014 meeting. If realized, this quantity of trade demand

would be just 19,872 pounds less than the quantity of Native spearmint oil available under the volume control levels implemented in January 2015 (1,463,771 pounds available prior to this rule minus 1,443,899 pounds demanded = 19,872 pounds). The increased quantity of Native spearmint oil (48,769 pounds) actually made available to the market as a result of this action would ensure that market demand is fully satisfied in the current year and that there would be approximately 68,641 pounds of Native spearmint oil salable inventory available to the market for the start of the 2015–2016 marketing year, which begins on June 1, 2015.

In making the recommendation to increase the salable quantity and allotment percentage of Native spearmint oil, the Committee considered all currently available information on the price, supply, and demand of spearmint oil. The Committee also considered reports and other information from handlers and producers in attendance at the meeting. Lastly, the Committee manager presented information and reports that were provided to the Committee staff by handlers and producers who were not in attendance at the February 18, 2015, meeting.

This action increases the 2014–2015 marketing year Native spearmint oil salable quantity by 71,143 pounds, to a total of 1,351,704 pounds. However, as mentioned previously, the net effect of the increase will be much less than the calculated increase due to the amount of actual oil individual producers have available to market from reserve pool inventory. The Committee estimates that this action will actually make an additional 48,769 pounds of Native spearmint oil available to the market. That amount, combined with the 89,872 pounds of salable Native spearmint oil that the Committee estimates is currently available to the market, will make a total of 138,641 pounds available to be marketed through the remainder of the marketing year. The total supply of Native spearmint oil that the Committee anticipates actually being available to the market over the course of the 2014–2015 marketing year will be increased to 1,512,540 pounds. Actual sales of Native spearmint oil for the 2013–2014 marketing year totaled 1,341,555 pounds.

The Committee estimates that this action will result in 68,641 pounds of salable Native spearmint oil being carried into the 2015–2016 marketing year. In addition, the Committee expects that 248,602 pounds of Native spearmint oil will still be held in reserve pool stocks by producers after this increase. These inventory levels are low in comparison to historical levels, but are well within the range that the Committee believes to be appropriate moving forward. In addition, the Committee believes that the current Native spearmint oil market situation will stimulate production of Native spearmint oil in the coming years, further ensuring that the market will be adequately supplied in the future.

As mentioned previously, when the original 2014–2015 marketing policy statement was drafted, handlers estimated the demand for Native spearmint oil for the 2014–2015 marketing year to be 1,300,000 pounds. The Committee's initial recommendation for the establishment of the Native spearmint oil salable quantity and allotment percentage for the 2014–2015 marketing year was based on that estimate. The Committee did not anticipate the increase in demand for Native spearmint oil that the market is currently experiencing and did not make allowances for it when the marketing policy was initially adopted. At the February 18, 2015, meeting, the Committee revised its estimate of the current trade demand to 1,443,899 pounds. The Committee now believes that the supply of Native spearmint oil available to the market under the previously revised salable quantity and allotment percentage would be insufficient to satisfy the current level of demand for oil at reasonable price levels. The Committee further believes that the increase in the salable quantity and allotment percentage effectuated by this action is vital to ensuring an adequate supply of Native spearmint oil is available to the market moving forward.

As previously stated, it is anticipated that this action will make 48,769 pounds of the Native spearmint oil held in the reserve pool available to the market. However, to achieve that desired net effect under the current supply conditions in the industry, it is necessary for the salable quantity and allotment percentage established under the volume regulation provisions of the order to be set at artificially high levels. The Committee records show that some producers do not hold Native spearmint oil in reserve. Given the process by which volume regulation is effectuated under the order, only those producers with Native spearmint oil in the reserve pool will be able to utilize the additional annual allotment that is issued as a result of this rule. Likewise, producers that do not have Native spearmint oil reserve oil from prior years' production will not have any Native spearmint oil inventory to offer to the market, regardless of how much additional annual allotment is issued to those producers. As such, the Committee expects that approximately 31 percent of the increased salable quantity and allotment percentage for Native spearmint oil may go unused.

As an example, assume Producer A has 2,000 pounds of Native spearmint oil allotment base. In addition, assume that during the 2014–2015 marketing year Producer A produced 920 pounds of Native spearmint oil and held 220 pounds of excess Native spearmint oil in reserve from production in prior years. Given that the initial 2014–2015 marketing year allotment percentage was established at 46 percent, Producer A could market all 920 pounds of the current year production (46 percent allotment percentage × 2,000 pounds of allotment base), leaving him/her with 220 pounds in the reserve pool that was initially not available to market. Without an increase in the allotment percentage, the producer would not have been able to market any of the 220 pounds of reserve oil and the oil would have continued to have been held in the reserve pool for marketing in subsequent years. For Producer A to market all 1,140 pounds of his/her current year Native spearmint oil production and reserve inventory, the allotment percentage needs to be increased by 11 percent (8 percent plus 3 percent) to a total of 57 percent (57 percent × 2,000 pounds = 1,140 pounds). An increase in the allotment percentage of anything less than 11 percent would fail to release all of the Native spearmint oil that the producer holds in the reserve pool. The increase in the allotment percentage may be accomplished in several steps, but has a cumulative effect with regards to the release of spearmint oil held in the reserve pool.

In contrast, assume that another producer, Producer B, likewise has 2,000 pounds of Native spearmint oil allotment base and produced 920 pounds of Native spearmint oil during the 2014–2015 marketing year. However, Producer B has no Native spearmint oil held in reserve. As in the first case, Producer B could market all of his/her current year production under the initial allotment percentage of 46 percent. However, any subsequent increase in the allotment percentage would have no impact on Producer B, as the producer has no reserve pool oil available to deliver to the market. As a result, any additional annual allotment allocated to Producer B after an increase in the allotment percentage would go unfilled.

The Committee acknowledges that the relatively high salable quantity, and the corresponding high allotment percentage, will create a quantity of Native spearmint oil annual allotment for which no Native spearmint oil will actually be available to market. The Committee estimates that a 3 percent increase in the allotment percentage and a 71,143 pound increase in the salable quantity is required to make the desired 48,769 pounds of Native spearmint reserve pool oil available to the market. Accordingly, the Committee expects that 22,374 pounds of the recommended 71,143 pound increase in salable quantity will go unfilled. This quantity of underutilized salable quantity has been factored into the Committee's recommendation.

The Committee's stated intent in the use of marketing order volume control regulation is to keep adequate supplies available to meet market needs and to maintain orderly marketing conditions. With that in mind, the Committee developed its recommendation for increasing the Native spearmint oil salable quantity and allotment percentage for the 2014–2015 marketing year based on the information discussed above, as well as the summary data outlined below.

(A) Estimated 2014–2015 Native Allotment Base—2,371,350 pounds. This is the estimate on which the original 2014–2015 salable quantity and allotment percentage was based.

(B) Revised 2014–2015 Native Allotment Base—2,371,410 pounds. This is 60 pounds more than the estimated allotment base of 2,371,350 pounds. The difference is the result of annual adjustments made to the allotment base according to the provisions of the order.

(C) Original 2014–2015 Native Allotment Percentage—46 percent. This was unanimously recommended by the Committee on November 6, 2013.

(D) Original 2014–2015 Native Salable Quantity—1,090,821 pounds. This figure is 46 percent of the original estimated 2014–2015 allotment base of 2,371,350 pounds.

(E) Adjusted Initial 2014–2015 Native Salable Quantity—1,090,849 pounds. This figure reflects the salable quantity actually available at the beginning of the 2014–2015 marketing year. This quantity is derived by applying the initial 46 percent allotment percentage to the revised allotment base of 2,371,410.

(F) First Revision to the 2014–2015 Native Salable Quantity and Allotment Percentage:

(1) Initial Increase in the Native Allotment Percentage—8 percent. The Committee recommended an 8 percent increase at its November 5, 2014, meeting. The revision was published in the **Federal Register** on January 22, 2015 (80 FR 3142).

(2) Revised 2014–2015 Native Allotment Percentage—54 percent. This number was derived by adding the increase of 8 percent to the initially established 2014–2015 allotment percentage of 46 percent.

(3) Revised 2014–2015 Native Salable Quantity—1,280,561 pounds. This amount is 54 percent of the revised 2014–2015 allotment base of 2,371,410 pounds.

(G) Second Revision to the 2014–2015 Native Salable Quantity and Allotment Percentage:

(1) Increase in Native Allotment Percentage—3 percent. The Committee unanimously recommended a 3 percent increase at its February 18, 2015, meeting.

(2) Revised 2014–2015 Native Allotment Percentage—57 percent. This number is derived by adding the 3 percent increase to the previously revised 2014–2015 allotment percentage of 54 percent.

(3) Revised 2014–2015 Native Salable Quantity—1,351,704 pounds. This amount is 57 percent of the revised 2014–2015 allotment base of 2,371,410 pounds.

(4) Computed Increase in the 2014–2015 Native Salable Quantity as a Result of this Revision—71,143 pounds. This figure is 3 percent of the revised 2014–2015 allotment base of 2,371,410 pounds.

(5) Expected Actual Increase in the 2014–2015 Native Spearmint Oil Available to the Market—48,769 pounds. This amount is based on the Committee's estimation of Native spearmint oil actually held in the reserve pool by producers that may enter the market as a result of this rule.

Scotch spearmint oil is also regulated by the order. As mentioned previously, a salable quantity and allotment percentage for Scotch spearmint oil was established in a final rule published in the **Federal Register** on May 8, 2014 (79 FR 26359) and subsequently increased in an interim rule published in the **Federal Register** on October 31, 2014 (79 FR 64657). At the February 18, 2015, meeting, the Committee considered the current production, inventory, and marketing conditions for Scotch spearmint oil. After receiving reports from the Committee staff and comments from the industry, the consensus of the Committee was that the previously increased salable quantity and allotment percentage for Scotch spearmint oil was appropriate for the current market conditions. As such, the Committee took no further action with regards to Scotch spearmint oil for the 2014–2015 marketing year.

This rule relaxes the regulation of Native spearmint oil and will allow producers to meet market demand while improving producer returns. In conjunction with the issuance of this rule, the Committee's revised marketing policy statement for the 2014–2015 marketing year has been reviewed by USDA. The Committee's marketing policy statement, a requirement whenever the Committee recommends implementing volume regulations or recommends revisions to existing volume regulations, meets the intent of § 985.50 of the order. During its discussion of revising the 2014–2015 salable quantities and allotment percentages, the Committee considered: (1) The estimated quantity of salable oil of each class held by producers and handlers; (2) the estimated demand for each class of oil; (3) the prospective production of each class of oil; (4) the total of allotment bases of each class of oil for the current marketing year and the estimated total of allotment bases of each class for the ensuing marketing year; (5) the quantity of reserve oil, by class, in storage; (6) producer prices of oil, including prices for each class of oil; and (7) general market conditions for each class of oil, including whether the estimated season average price to producers is likely to exceed parity. Conformity with USDA's ''Guidelines for Fruit, Vegetable, and Specialty Crop Marketing Orders'' has also been reviewed and confirmed.

The increase in the Native spearmint oil salable quantity and allotment percentage allows for anticipated market needs for that class of oil. In determining anticipated market needs, the Committee considered changes and trends in historical sales, production, and demand.

Initial 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 initial 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 the 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 8 spearmint oil handlers subject to regulation under the order, and approximately 39 producers of Scotch spearmint oil and approximately 91 producers of Native spearmint oil in the regulated production area. Small agricultural service firms are defined by the Small Business Administration (SBA) as those having annual receipts of less than $7,000,000, and small agricultural producers are defined as those having annual receipts of less than $750,000 (13 CFR 121.201).

Based on the SBA's definition of small entities, the Committee estimates that only two of the eight handlers regulated by the order could be considered small entities. Most of the handlers are large corporations involved in the international trading of essential oils and the products of essential oils. In addition, the Committee estimates that 22 of the 39 Scotch spearmint oil producers and 29 of the 91 Native spearmint oil producers could be classified as small entities under the SBA definition. Thus, the majority of handlers and producers of Far West spearmint oil may not be classified as small entities.

The use of volume control regulation allows the spearmint oil industry to fully supply spearmint oil markets while avoiding the negative consequences of over-supplying these markets. Without volume control regulation, the supply and price of spearmint oil would likely fluctuate widely. Periods of oversupply could result in low producer prices and a large volume of oil stored and carried over to future crop years. Periods of undersupply could lead to excessive price spikes and could drive end users to source flavoring needs from other markets, potentially causing long-term economic damage to the domestic spearmint oil industry. The marketing order's volume control provisions have been successfully implemented in the domestic spearmint oil industry since 1980 and provide benefits for producers, handlers, manufacturers, and consumers.

This rule increases the quantity of Native spearmint oil that handlers may purchase from, or handle on behalf of, producers during the 2014–2015 marketing year, which ends on May 31, 2015. The 2014–2015 Native spearmint oil salable quantity was initially established at 1,090,821 pounds and the allotment percentage initially set at 46 percent. The salable quantity was subsequently increased to 1,280,561 pounds and the allotment percentage to 54 percent. This rule further increases the Native spearmint oil salable quantity to 1,351,704 pounds and the allotment percentage to 57 percent.

Based on the information and projections available at the February 18, 2015, meeting, the Committee considered a number of alternatives to this increase. The Committee not only considered leaving the salable quantity and allotment percentage unchanged, but also considered other potential levels of increase. The Committee reached its recommendation to increase the salable quantity and allotment percentage for Native spearmint oil after careful consideration of all available information and input from all interested industry participants, and believes that the levels recommended will achieve the objectives sought. Without the increase, the Committee believes the industry would not be able to satisfactorily meet market demand.

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. 0581–0178, Vegetable and Specialty Crop Marketing Orders. 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 rule will not impose any additional reporting or recordkeeping requirements on either small or large spearmint oil 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.

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, USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this rule.

Further, the Committee's meeting was widely publicized throughout the spearmint oil industry, and all interested persons were invited to attend the meeting and participate in Committee deliberations. Like all Committee meetings, the February 18, 2015, meeting was a public meeting, and all entities, both large and small, were able to express their views on this issue. Finally, interested persons are invited to submit information on the regulatory and informational impacts of this action on small businesses.

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.

This rule invites comments on a change to the salable quantity and allotment percentage for Native spearmint oil for the 2014–2015 marketing year. Any comments received will be considered prior to finalization of this rule.

After consideration of all relevant material presented, including the Committee's recommendation, and other information, it is found that this interim rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) This rule increases the quantity of Native spearmint oil that may be marketed during the marketing year, which ends on May 31, 2015; (2) the current quantity of Native spearmint oil may be inadequate to meet demand for the 2014–2015 marketing year, thus making the additional oil available as soon as is practicable will be beneficial to both handlers and producers; (3) the Committee recommended these changes at a public meeting and interested parties had an opportunity to provide input; and (4) this rule provides a 60-day comment period, and any comments received will be considered prior to finalization of this rule.

List of Subjects in 7 CFR Part 985

Marketing agreements, Oils and fats, Reporting and recordkeeping requirements, Spearmint oil.

For the reasons set forth in the preamble, 7 CFR part 985 is amended as follows:

PART 985—MARKETING ORDER REGULATING THE HANDLING OF SPEARMINT OIL PRODUCED IN THE FAR WEST

■ 1. The authority citation for 7 CFR part 985 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. In § 985.233, revise paragraph (b) to read as follows:

§ 985.233 Salable quantities and allotment percentages—2014–2015 marketing year.

* * * * *

(b) Class 3 (Native) oil—a salable quantity of 1,351,704 pounds and an allotment percentage of 57 percent.

Dated: March 24, 2015.

Rex A. Barnes,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2015–07114 Filed 3–27–15; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 985

[Doc. No. AMS–FV–13–0087; FV14–985–1A FIR]

Marketing Order Regulating the Handling of Spearmint Oil Produced in the Far West; Revision of the Salable Quantity and Allotment Percentage for Class 1 (Scotch) Spearmint Oil for the 2014–2015 Marketing Year

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: The Department of Agriculture (USDA) is adopting as a final rule, without change, an interim rule recommended by the Spearmint Oil Administrative Committee (Committee) that revised the quantity of Class 1 (Scotch) spearmint oil that handlers may purchase from or handle on behalf of, producers during the 2014–2015 marketing year under the Far West spearmint oil marketing order. The Committee locally administers the order and is comprised of producers and handlers of spearmint oil. The interim rule increased the Scotch spearmint oil salable quantity from 1,149,030 pounds to 1,984,423 pounds and the allotment percentage from 55 percent to 95 percent. This change is expected to help maintain orderly marketing conditions in the Far West spearmint oil market.

DATES: Effective March 30, 2015.

FOR FURTHER INFORMATION CONTACT: Barry Broadbent, Senior Marketing Specialist, or Gary Olson, Regional Director, Northwest Marketing Field Office, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA; Telephone: (503) 326–2724, Fax: (503) 326–7440, or Email: *Barry.Broadbent@ams.usda.gov* or *GaryD.Olson@ams.usda.gov.*

Small businesses may obtain information on complying with this and other marketing order regulations by viewing a guide at the following Web site: *http://www.ams.usda.gov/MarketingOrdersSmallBusinessGuide*; or 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.Smutny@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Order No. 985 (7 CFR part 985), as amended, regulating the handling of spearmint oil produced in the Far West (Washington, Idaho, Oregon, and designated parts of Nevada and Utah), 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 rule in conformance with Executive Orders 12866, 13563, and 13175.

The handling of spearmint oil produced in the Far West is regulated by the order and is administered locally by the Committee. Under the authority of the order, salable quantities and allotment percentages were established for both Scotch and Native spearmint oil for the 2014–2015 marketing year. However, early in the 2014–2015 marketing year, it became evident to the Committee and the industry that demand for Scotch spearmint oil was greater than previously projected and an intra-seasonal increase in the salable quantity and allotment percentage for Scotch spearmint oil was necessary to adequately supply the increased demand. Therefore, this rule continues in effect the rule that increased the Scotch spearmint oil salable quantity from 1,149,030 pounds to 1,984,423 pounds and the allotment percentage from 55 percent to 95 percent.

In an interim rule published in the **Federal Register** on October 31, 2014, and effective June 1, 2014, through May 31, 2015 (79 FR 64657, Doc. No. AMS–FV–13–0087, FV14–985–1A IR), § 985.233 was amended to reflect the aforementioned increases in the salable quantity and allotment percentage for Scotch spearmint oil for the 2014–2015 marketing year.

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 the 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 8 spearmint oil handlers subject to regulation under the order, and approximately 39 producers of Scotch spearmint oil and approximately 91 producers of Native spearmint oil in the regulated production area. Small agricultural service firms are defined by the Small Business Administration (SBA) as those having annual receipts of less than $7,000,000, and small agricultural producers are defined as those having annual receipts of less than $750,000 (13 CFR 121.201).

Based on the SBA's definition of small entities, the Committee estimates that only two of the eight handlers regulated by the order could be considered small entities. Most of the handlers are large corporations involved in the international trading of essential oils and the products of essential oils. In addition, the Committee estimates that 22 of the 39 Scotch spearmint oil producers and 29 of the 91 Native spearmint oil producers could be classified as small entities under the SBA definition. Thus, the majority of handlers and producers of Far West spearmint oil may not be classified as small entities.

The use of volume control regulation allows the spearmint oil industry to fully supply spearmint oil markets while avoiding the negative consequences of over-supplying these markets. Without volume control regulation, the supply and price of spearmint oil would likely fluctuate widely. Periods of oversupply could result in low producer prices and a large volume of oil stored and carried over to future crop years. Periods of undersupply could lead to excessive price spikes and could drive end users to source their flavoring needs from other markets, potentially causing long-term economic damage to the domestic spearmint oil industry. The order's volume control provisions have been successfully implemented in the domestic spearmint oil industry since 1980 and provide benefits for producers, handlers, manufacturers, and consumers.

This rule increases the quantity of Scotch spearmint oil that handlers may purchase from or handle on behalf of producers during the 2014–2015 marketing year, which ends on May 31, 2015. The 2014–2015 Scotch spearmint oil salable quantity was initially established at 1,149,030 pounds and the allotment percentage initially set at 55 percent. This rule increases the Scotch spearmint oil salable quantity to 1,984,423 pounds and the allotment percentage to 95 percent.

The Committee reached its decision to recommend an increase in the salable quantity and allotment percentage for Scotch spearmint oil after careful consideration of all available information. With the increase, the Committee believes that the industry will be able to satisfactorily meet the current market demand for this class of spearmint oil. This rule amends the salable quantities and allotment percentages previously established in § 985.233. Authority for this action is provided in §§ 985.50, 985.51, and 985.52 of the order.

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. 0581–0178, Vegetable and Specialty Crop Marketing Orders. 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 rule will not impose any additional reporting or recordkeeping requirements on either small or large spearmint oil 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. In addition, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

Further, the Committee's meeting was widely publicized throughout the spearmint oil industry and all interested persons were invited to attend the meeting and participate in Committee deliberations. Like all Committee meetings, the September 11, 2014, meeting was a public meeting and all entities, both large and small, were able to express their views on this issue.

Comments on the interim rule were required to be received on or before December 30, 2014. No comments were received. Therefore, for the reasons given in the interim rule, we are adopting the interim rule as a final rule, without change.

To view the interim rule, go to: *http://www.regulations.gov/#!documentDetail;D=AMS-FV-13-0087-0003.*

This action also affirms information contained in the interim rule concerning Executive Orders 12866, 12988, 13175, and 13563; the Paperwork Reduction Act (44 U.S.C. Chapter 35); and the E-Gov Act (44 U.S.C. 101).

After consideration of all relevant material presented, it is found that finalizing the interim rule, without change, as published in the **Federal Register** (79 FR 64657, October 31, 2014) will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 985

Marketing agreements, Oils and fats, Reporting and recordkeeping requirements, Spearmint oil.

Accordingly, the interim rule that amended 7 CFR part 985 and that was published at 79 FR 64657 on October 31, 2014, is adopted as a final rule, without change.

Dated: March 24, 2015.

Rex A. Barnes,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2015–07110 Filed 3–27–15; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–1002; Directorate Identifier 2014–CE–033–AD; Amendment 39–18127; AD 2015–06–09]

RIN 2120–AA64

Airworthiness Directives; Pacific Aerospace Limited Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for Pacific Aerospace Limited (PAL) Model 750XL airplanes. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as PAL Model 750XL airplanes manufactured with only one attitude indicator. A second attitude indicator is required for flights under instrument flight rules. We are issuing this AD to require actions to address the unsafe condition on these products.

DATES: This AD is effective May 4, 2015.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of May 4, 2015.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–1002; or in person at Document 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 service information identified in this AD, contact Pacific Aerospace Limited, Airport Road, Private Bag 3027, Hamilton 3240, New Zealand; telephone: +64 7 843 6144; fax: +64 7 843 6134; email: *pacific@aerospace.co.nz;* Internet: *http://www.aerospace.co.nz/.* You may view this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–1002.

FOR FURTHER INFORMATION CONTACT: Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4123; fax: (816) 329–4090; email: *karl.schletzbaum@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to add an AD that would apply to Pacific Aerospace Limited Model 750XL airplanes. The NPRM was published in the **Federal Register** on December 8, 2014 (79 FR 72564). The NPRM proposed to correct an unsafe condition for the specified products and was based on mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country. The MCAI states:

> This AD with effective date 10 November 2014 is prompted by a recent determination that certain PAL750XL aircraft were inadvertently manufactured with instrument panels with only one Attitude Indicator (AI). A second AI is required for PAL750XL operating under Instrument Flight Rules (IFR).

The AD mandates the installation of either a second AI, or the enablement of Reversionary Attitude mode in the Sandel Electronic Horizontal Situation Indicator (EHSI), if fitted, when operating under IFR.

The MCAI can be found in the AD docket on the Internet at: *http://www.regulations.gov/#!documentDetail;D=FAA-2014-1002-0002.*

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (79 FR 72564, December 8, 2014) or on the determination of the cost to the public.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting the AD as proposed 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 72564, December 8, 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 72564, December 8, 2014).

Relative Service Information Under 1 CFR part 51

We reviewed Pacific Aerospace Limited Mandatory Service Bulletin PACSB/XL/074, Issue 2, dated November 4, 2014. The service bulletin describes procedures for installing a second attitude indicator or enabling the reversionary mode on a Sandel SN3500 electronic horizontal situation indicator (EHSI), if installed, whichever is applicable. This service information is reasonably available; see **ADDRESSES** for ways to access this service information.

Costs of Compliance

We estimate that this AD will affect 17 products of U.S. registry. We also estimate that it would take about 6 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Required parts would cost about $3,500 per product.

Based on these figures, we estimate the cost of the AD on U.S. operators to be $68,170, or $4,010 per product.

Authority for This Rulemaking

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

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

Regulatory Findings

We determined that this 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 this AD:

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

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

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

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

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–2014–1002; 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 the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

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 AD:

2015–06–09 Pacific Aerospace Limited: Amendment 39–18127; Docket No. FAA–2014–1002; Directorate Identifier 2014–CE–033–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective May 4, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Pacific Aerospace Limited Model 750XL airplanes, all serial numbers, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 34: Navigation.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as Pacific Aerospace Limited Model 750XL airplanes manufactured with instrument panels with only one attitude indicator. A second attitude indicator is required to operate under instrument flight rules (IFR). A reversionary attitude indicator reduces the probability of a single point failure, which could result in loss of control. We are issuing this proposed AD to install a reversionary attitude indicator before operating in IFR conditions.

(f) Actions and Compliance

Unless already done, before the next flight requiring instrument flight rules (IFR) after the effective date of this AD, install a second attitude indicator into the right hand instrument panel or enable the reversionary mode on a Sandel SN3500 electronic horizontal situation indicator (EHSI), if installed, whichever is applicable, following the ACCOMPLISHMENT INSTRUCTIONS in Pacific Aerospace Limited Mandatory Service Bulletin PACSB/XL/074, Issue 2, dated November 4, 2014.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Karl Schletzbaum, Aerospace Engineer, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4123; fax: (816) 329–4090; email:

karl.schletzbaum@faa.gov. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(h) Related Information

Refer to MCAI in Civil Aviation Authority (CAA) AD DCA/750XL/17A, dated November 6, 2014, for related information. The MCAI can be found in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2014-1002-0002.*

(i) 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) Pacific Aerospace Limited Mandatory Service Bulletin PACSB/XL/074, Issue 2, dated November 4, 2014.

(ii) Reserved.

(3) For service information identified in this AD, contact Pacific Aerospace Limited, Airport Road, Private Bag 3027, Hamilton 3240, New Zealand; telephone: +64 7 843 6144; fax: +64 7 843 6134; email: *pacific@aerospace.co.nz;* Internet: *http://www.aerospace.co.nz/.*

(4) You may view this service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. In addition, you can access this service information on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–1002.

(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 Kansas City, Missouri, on March 19, 2015.

Pat Mullen,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–07104 Filed 3–27–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0619; Directorate Identifier 2014–NM–029–AD; Amendment 39–18124; AD 2015–06–06]

RIN 2120–AA64

Airworthiness Directives; BAE Systems (Operations) Limited Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all BAE Systems (Operations) Limited Model 4101 airplanes. This AD was prompted by a report of the failure, due to overheat, of a bracket on which the earth post (EP) for the generator and propeller de-ice systems is located. This AD requires an inspection of the affected EPs and attachment structure for damage, an inspection of the earth cables of the generator and propeller de-ice system for signs of overheating and arcing damage, a torque check of the affected EP stiff nuts, an electrical high current bonding check of the bracket, and corrective actions if necessary. We are issuing this AD to detect and correct an overheat failure of the EPs for the generator and propeller de-ice system, and possible degradation of the wing front spar cap and/or web, which could affect the structural integrity of the wing.

DATES: This AD becomes effective May 4, 2015.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of May 4, 2015.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2014-0619* or in person at the 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.

For service information identified in this AD, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone +44 1292 675207; fax +44 1292 675704; email *RApublications@baesystems.com;* Internet *http://www.baesystems.com/Businesses/Regional Aircraft/index.htm.* 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. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA 2014–0619.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1175; fax 425–227–1149.

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 all BAE Systems (Operations) Limited Model 4101 airplanes. The NPRM published in the **Federal Register** on September 3, 2014 (79 FR 52270). The NPRM was prompted by a report of the failure, due to overheat, of a bracket on which the EP for the generator and propeller de-ice systems is located. The NPRM proposed to require an inspection of the affected EPs and attachment structure for damage, an inspection of the earth cables of the generator and propeller de-ice system for signs of overheating and arcing damage, a torque check of the affected EP stiff nuts, an electrical high current bonding check of the bracket, and corrective actions if necessary. We are issuing this AD to detect and correct an overheat failure of the EPs for the generator and propeller de-ice system, and possible degradation of the wing front spar cap and/or web, which could affect the structural integrity of the wing.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2014–0006, dated January 7, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition. The MCAI states:

> An occurrence was reported involving a Jetstream 4100 aeroplane, where a bracket, on which the earth post for the generator and propeller de-ice systems is located, failed due to overheat. Although the earth post and cables were not damaged, the mounting bracket and underlying structure were damaged to the extent that repair of the wing front spar web was necessary. Furthermore, the aft engine cross support rod, which is attached to the same bracket, was found damaged, as a result of excessive current

load, and required replacement. The subsequent investigation determined that, due to the damage tolerance of the aft engine cross rod support, the rod does not present an airworthiness issue. However, as a consequence of overheat failure of the earth post, degradation of the wing front spar cap and/or web could affect the structural integrity of the wing.

This condition, if not detected and corrected, could reduce the capacity of the wing to support loads, possibly resulting in wing structure failure and consequent loss of the aeroplane.

To address this potential unsafe condition, BAE Systems (Operations) Ltd issued [Inspection] Service Bulletin (SB) J41–24–043 [Revision 2, dated August 21, 2013] to provide inspection instructions.

For the reasons described above, this [EASA] AD requires a one-time visual inspection of the affected earth posts, an electrical high current bonding check of the bracket and, if discrepancies are detected, accomplishment of applicable corrective action(s).

The required actions include a general visual inspection of the affected EPs and attachment structure for damage; a general visual inspection of the earth cables of the generator and propeller de-ice system for arcing damage and signs of overheating of the cable insulation and terminal tags; a torque check of the EP2 and EP4 stiff nuts; an electrical high current bonding check of the bracket; and corrective actions if necessary. Corrective actions include repair of damaged structure, replacement of damaged cables, cleaning of all applicable surfaces to achieve the necessary resistance value, and correction of the torque load of EP stiff nuts.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2014-0619-0002.*

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (79 FR 52270, September 3, 2014) or on the determination of the cost to the public.

Changes Made to This AD

BAE Systems (Operations) Limited has issued Inspection Service Bulletin J41–24–043, Revision 3, dated June 16, 2014. This service bulletin states that ''this revision does not require rework of the modification(s) embodied by earlier revision of this service bulletin.'' We have revised paragraphs (g) through (k) of this AD to reference this service information. We have revised paragraph (l) of this AD to give credit for actions done prior to the effective date of this AD using BAE Systems (Operations) Limited Inspection Service Bulletin J41–24–043, Revision 2, dated August 21, 2013.

Conclusion

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

- Are consistent with the intent that was proposed in the NPRM (79 FR 52270, September 3, 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 52270, September 3, 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 BAE Systems (Operations) Limited Service Bulletin J41–24–043, Revision 3, dated June 16, 2014. The service information describes procedures for an inspection of the earth post EP2 (left) and earth post EP4 (right) on the structure for the left and right power plants. This service information is reasonably available; see **ADDRESSES** for ways to access this service information.

Costs of Compliance

We estimate that this AD affects 4 airplanes of U.S. registry.

We also estimate that it would take about 4 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $1,360, or $340 per product.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this AD.

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 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 the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2014-0619;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section.

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):

2015–06–06 BAE Systems (Operations) Limited: Amendment 39–18124. Docket No. FAA–2014–0619; Directorate Identifier 2014–NM–029–AD.

(a) Effective Date

This AD becomes effective May 4, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to BAE Systems (Operations) Limited Model 4101 airplanes, certificated in any category, all serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 24, Electrical Power.

(e) Reason

This AD was prompted by a report of the failure, due to overheat, of a bracket on which the earth post (EP) for the generator and propeller de-ice systems is located. We are issuing this AD to detect and correct an overheat failure of the EPs for the generator and propeller de-ice system and possible degradation of the wing front spar cap and/or web, which could affect the structural integrity of the wing.

(f) Compliance

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

(g) Inspection of the Earth Posts and Attachment Structure and Corrective Action

Within 6 months after the effective date of this AD: Do a general visual inspection on both engines of the structure around EP2 and EP4; the brackets on which the EPs are mounted; the attachment of the nacelle horizontal support for damage, and lateral movement of the EPs; in accordance with the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin J41–24–043, Revision 3, dated June 16, 2014. If any lateral movement of the EP or any other damage is detected, before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or BAE Systems (Operations) Limited's EASA Design Organization Approval (DOA).

(h) Inspection of the Earth Cables and Corrective Action

Within 6 months after the effective date of this AD: Do a general visual inspection of the earth cables of the generator and propeller de-ice system for arcing damage and signs that the cable insulation or terminal tags have been overheated, and do all applicable corrective actions; in accordance with the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin J41–24–043, Revision 3, dated June 16, 2014. Do all applicable corrective actions before further flight.

(i) Torque Check of the Earth Post Stiff Nuts

Within 6 months after the effective date of this AD: Do a torque check of the EP2 and EP4 stiff nuts, and adjust the torque load as applicable, in accordance with the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin J41–24–043, Revision 3, dated June 16, 2014.

(j) Resistance Measurement of the EP2 and EP4 Earth Bolts

Within 6 months after the effective date of this AD: Measure the resistance of the EP2 and EP4 earth bolts using a high-current millivolts-drop test, and do all applicable corrective actions, in accordance with the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin J41–24–043, Revision 3, dated June 16, 2014. Do all applicable corrective actions before further flight.

(k) No Reporting Required

Although BAE Systems (Operations) Limited Inspection Service Bulletin J41–24–043, Revision 3, dated June 16, 2014, specifies to submit information to the manufacturer, this AD does not require that this information be submitted.

(l) Credit for Previous Actions

This paragraph provides credit for actions required by paragraphs (g), (h), (i), and (j) of this AD, if those actions were performed before the effective date of this AD using a service bulletin specified in paragraph (l)(1), (l)(2), or (l)(3) of this AD, which are not incorporated by reference in this AD.

(1) BAE Systems (Operations) Limited Inspection Service Bulletin J41–24–043, dated September 27, 2011.

(2) BAE Systems (Operations) Limited Inspection Service Bulletin J41–24–043, Revision 1, dated January 16, 2012.

(3) BAE Systems (Operations) Limited Inspection Service Bulletin J41–24–043, Revision 2, dated August 21, 2013.

(m) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1175; fax 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) Contacting the Manufacturer: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or BAE Systems (Operations) Limited's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(n) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) European Aviation Safety Agency Airworthiness Directive 2014–0006, dated January 7, 2014, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2014-0619-0002.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (o)(3) and (o)(4) of this AD.

(o) 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 this AD specifies otherwise.

(i) BAE Systems (Operations) Limited Inspection Service Bulletin J41–24–043, Revision 3, dated June 16, 2014.

(ii) Reserved.

(3) For service information identified in this AD, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone +44 1292 675207; fax +44 1292 675704; email *RApublications@baesystems.com;* Internet *http://www.baesystems.com/Businesses/RegionalAircraft/index.htm.*

(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 March 12, 2015.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–06751 Filed 3–27–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0284; Directorate Identifier 2014–NM–011–AD; Amendment 39–18125; AD 2015–06–07]

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 737–100, 737–200, 737–200C, 737–300, 737–400, and 737–500 series airplanes. This AD was prompted by reports of cracking in the lower corners of the forward entry doorway and the upper corners of the airstairs cutout. This AD requires inspections for cracking of the forward entry doorway and airstairs cutout, and corrective actions if necessary. This AD also provides terminating action for the repetitive inspections. We are issuing this AD to detect and correct cracks in the lower corners of the forward entry door cutout and the upper corners of the airstairs cutout, which could progress and result in an inability to maintain cabin pressurization.

DATES: This AD is effective May 4, 2015.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of May 4, 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, WA. 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–2014–0284.

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–2014–0284; 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: Nenita Odesa, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5234; fax: 562–627–5210; email: *nenita.odesa@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 737–100, 737–200, 737–200C, 737–300, 737–400, and 737–500 series airplanes. The NPRM published in the **Federal Register** on May 28, 2014 (79 FR 30500). The NPRM was prompted by reports of cracking in the lower corners of the forward entry doorway and the upper corners of the airstairs cutout. The NPRM proposed to require inspections for cracking of the forward entry doorway and airstairs cutout, and corrective actions if necessary. The NPRM also proposed to provide terminating action for the repetitive inspections. We are issuing this AD to detect and correct cracks in the lower corners of the forward entry door cutout and the upper corners of the airstairs cutout, which could progress and result in an inability to maintain cabin pressurization.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM (79 FR 30500, May 28, 2014) and the FAA's response to each comment.

Effect of Winglets on Accomplishment of the Proposed Actions

Aviation Partners Boeing stated that accomplishing the installation of winglets per supplemental type certificate (STC) ST01219SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/082838ee177dbf62862576a4005cdfc0/$FILE/ST01219SE.pdf*) does not affect the actions specified in the NPRM (79 FR 30500, May 28, 2014).

We concur with the commenter. We have redesignated paragraph (c) of the proposed AD (79 FR 30500, May 28, 2014) as paragraph (c)(1) in this AD and added new paragraph (c)(2) to this AD to state that installation of STC ST01219SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/082838ee177dbf62862576a4005cdfc0/$FILE/ST01219SE.pdf*) does not affect the ability to accomplish the actions required by this final rule. Therefore, for airplanes on which STC ST01219SE is installed, a ''change in product'' alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

Request to Clarify That Certain Inspections Are Not Required for Areas With Existing Repairs

Southwest Airlines (SWA) requested that the NPRM (79 FR 30500, May 28, 2014) be revised to clarify that the initial and repetitive inspections specified in paragraph (g)(1) of the proposed AD would not be required for locations that are common to existing repairs that were installed using the Boeing Model 737 structural repair manual (SRM) repairs identified in Part 3, ''Permanent Repair,'' of Paragraph 3.B., ''Work Instructions,'' of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–53–1083, Revision 4, dated December 18, 2013. As an alternative to this clarification, SWA suggested that guidance be provided on how to address the existing repairs since the inspections proposed in paragraph (g)(1) of the proposed AD cannot be accomplished in the repaired areas.

SWA observed that the applicability blocks in Repair 12 and Repair 13 of Boeing 737–300/400/500 SRM 53–10–01 state that the inspections identified in Boeing Special Attention Service Bulletin 737–53–1083, Revision 4, dated December 18, 2013, are not necessary for the repaired areas.

We agree that the inspections required by paragraph (g)(1) of this AD cannot be accomplished at locations where certain repairs have been installed. We have added a new paragraph (g)(3) to this AD and redesignated the subsequent paragraph as (g)(4). Paragraph (g)(3) of this AD clarifies that accomplishment of a permanent repair terminates the repetitive inspections required by paragraph (g)(1) of this AD for the repaired area only.

Request for Alternative Inspection Methods

SWA requested that the NPRM (79 FR 30500, May 28, 2014) be revised to

provide operators the option to request alternative inspection instructions from Boeing for areas with existing repairs that were approved by a Boeing Authorized Representative (AR). The inspections proposed in paragraph (g)(1) of the NPRM cannot be accomplished in areas with existing repairs.

We do not agree to revise this AD to include a provision to provide operators the option to request alternative inspection instructions from Boeing. If there are existing repairs that were approved by a Boeing AR, and those existing repairs prevent accomplishment of the inspections required by paragraph (g)(1) of this AD, 14 CFR 39.17 of the Federal Aviation Regulations requires an affected operator to obtain an AMOC from the FAA. Upon publication of this AD, the Manager of the Los Angeles Aircraft Certification Office will consider granting AMOC authority for this AD to the Boeing Commercial Airplanes Organization Designation Authorization (ODA).

Request To Clarify That Inspections Are Not Required for Previously Repaired Areas

Boeing requested that paragraph (g)(2) of the NPRM (79 FR 30500, May 28, 2014) be revised to specify that the inspections required by paragraph (g)(1) of the NPRM are not required for Groups 1 and 2 airplanes that have been repaired using the service information identified in paragraph (g)(2)(i), (g)(2)(ii), or (g)(2)(iii) of the NPRM. Boeing noted that, as currently written, paragraph (g)(2) of the NPRM would not require inspection of the unrepaired lower entry door and upper airstair corners and would contradict the inspections in the service information, which could lead to an unsafe condition. Boeing also pointed out that the inspection zones specified in the following service information do not include the repaired area(s).

- Boeing Service Bulletin 737–531083, Revision 1, dated October 25, 1985.
- Boeing Service Bulletin 737–531083, Revision 2, dated March 17, 1988.
- Boeing Service Bulletin 737–531083, Revision 3, dated December 7, 1989.

For the reasons provided by the commenter we agree to revise paragraph (g)(2) of this AD to specify that ''[T]he inspections required by paragraph (g)(1) of this AD are not required in the repaired area.''

Request To Specify Inspection Locations

Boeing requested that paragraph (g)(1) of the NPRM (79 FR 30500, May 28, 2014) be revised to specify the locations that need to be inspected. The commenter stated that, as currently written, the inspection methods are specified but not the inspection locations. Boeing Special Attention Service Bulletin 737–53–1083, Revision 4, dated December 18, 2013, provides different inspection methods based on the location of the inspection. Boeing suggested that the revision to paragraph (g)(1) state ''[D]o the inspections specified in paragraphs (g)(1)(i), (g)(1)(ii), (g)(1)(iii), and (g)(1)(iv) of this AD and in accordance with Part 1 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–53–1083, Revision 4. . . .''

We do not agree it is necessary to specify inspection locations because paragraph (g)(1) of this AD already requires operators to do the inspections in accordance with Part 1 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–53–1083, Revision 5, dated July 22, 2014. These accomplishment instructions include the specific inspection methods and the inspection locations. No change has been made to this AD in this regard.

Request To Refer to Revised Service Information

ANA and Europe Airpost requested that the material in Boeing Information Notice 737–53–1083 R04 IN 03 to Boeing Alert Service Bulletin 737–53–1083 be included in the final rule. The commenters noted that, based on the material in Boeing Information Notice 737–53–1083 R04 IN 03 to Boeing Service Bulletin 737–53–1083, the inspection of the skin doubler required by paragraph (g)(1)(iii) of the NPRM (79 FR 30500, May 28, 2014) would no longer be applicable to Group 4 airplanes. The commenters explained that Boeing Special Attention Service Bulletin 737–53–1083, Revision 5, dated July 22, 2014, would incorporate the material in Boeing Information Notice 737–53–1083 R04 IN 03. The commenters pointed out that operators might have to request AMOCs from the FAA if the final rule did not include this material and was issued prior to Boeing's release of Boeing Special Attention Service Bulletin 737–53–1083, Revision 5, dated July 22, 2014.

We agree that the material in Information Notice 737–53–1083 R04 IN 03 to Boeing Service Bulletin 737–53–1083 is incorporated in Boeing Special Attention Service Bulletin 737–53–1083, Revision 5, dated July 22, 2014. Since the NPRM (79 FR 30500, May 28, 2014) was published, Boeing has issued and we have reviewed Special Attention Service Bulletin 737–53–1083, Revision 5, dated July 22, 2014. We have revised this AD to include Boeing Special Attention Service Bulletin 737–53–1083, Revision 5, dated July 22, 2014, as an additional source of service information. We have also included a new paragraph (k) in this AD, and redesignated the subsequent paragraphs accordingly, to provide credit for accomplishment of certain actions before the effective date of this AD using Boeing Special Attention Service Bulletin 737–53–1083, Revision 4, dated December 18, 2013.

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 and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (79 FR 30500, May 28, 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 30500, May 28, 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 737–53–1083, Revision 5, dated July 22, 2014. The service information describes procedures for inspection of the forward entry doorway and airstairs doorway, modification, and repair. This service information is reasonably available; see **ADDRESSES** for ways to access this service information.

Costs of Compliance

We estimate that this AD affects 132 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
Inspection (Groups 1 through 4 airplanes). [1]	9 work-hours × $85 per hour = $765 per inspection cycle.	$0	$765 per inspection cycle	$100,980 per inspection cycle.

[1] We have received no definitive data that would enable us to provide cost estimates for the inspection of Group 5 airplanes.

OPTIONAL COSTS

Action	Labor cost	Parts cost	Cost per product
Preventive modification	Up to 2 work-hours × $85 per hour = $170	Up to $3,927	Up to $4,097.

We estimate the following costs to do any necessary repair that would be required based on the results of the inspections. We have no way of determining the number of aircraft that might need this repair:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Repair	25 work-hours × $85 per hour = $2,125	Up to $5,342	Up to $7,467.

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):

2015–06–07 The Boeing Company: Amendment 39–18125; Docket No. FAA–2014–0284; Directorate Identifier 2014–NM–011–AD.

(a) Effective Date

This AD is effective May 4, 2015.

(b) Affected ADs

None.

(c) Applicability

(1) This AD applies to The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes, certificated in any category, as identified in Boeing Special Attention Service Bulletin 737–53–1083, Revision 5, dated July 22, 2014.

(2) Installation of Supplemental Type Certificate (STC) ST01219SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/082838ee177dbf62862576a4005cdfc0/$FILE/ST01219SE.pdf*) does not affect the ability to accomplish the actions required by this AD. For airplanes on which STC ST01219SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/ebd1cec7b301293e86257cb30045557a/$FILE/ST01219SE.pdf*) is installed, therefore, a ''change in product'' alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by reports of cracking in the lower corners of the forward entry doorway and the upper corners of the airstairs cutout. We are issuing this AD to detect and correct cracks in the lower corners of the forward entry door cutout and the upper corners of the airstairs cutout, which could progress and result in an inability to maintain cabin pressurization.

(f) Compliance

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

(g) Inspections and Corrective Actions

(1) For airplane Groups 1 through 4, as identified in Boeing Special Attention Service Bulletin 737–53–1083, Revision 5, dated July 22, 2014: Except as required by paragraph (j)(1) of this AD, at the applicable

time specified in table 1, 2, or 3, as applicable, of paragraph 1.E., ''Compliance,'' of Boeing Special Attention Service Bulletin 737 53–1083, Revision 5, dated July 22, 2014, do the inspections specified in paragraphs (g)(1)(i), (g)(1)(ii), (g)(1)(iii), and (g)(1)(iv) of this AD for cracks at the forward entry doorway and airstairs cutout, and do all applicable corrective actions, in accordance with Parts 1 and 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–53–1083, Revision 5, dated July 22, 2014, except as required by paragraph (j)(2) of this AD. Repeat the inspections, thereafter, at the interval specified in table 1, 2, or 3, as applicable, of paragraph 1.E., ''Compliance,'' of Boeing Special Attention Service Bulletin 737–53–1083, Revision 5, dated July 22, 2014. Do all applicable corrective actions before further flight. Any repair done in accordance with Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–53–1083, Revision 5, dated July 22, 2014, terminates the repetitive inspections required by paragraph (g)(1) of this AD for the repaired area only.

(i) An external detailed and high frequency eddy current (HFEC) inspection of the skin.

(ii) An internal detailed and HFEC inspection of exposed parts of the bear strap.

(iii) A detailed and HFEC inspection along the edge of the cutout in the skin, skin doubler, and bear strap.

(iv) An external low frequency eddy current inspection (LFEC) of the skin and bearstrap.

(2) For Groups 1 and 2 airplanes that have been repaired using any of the service information identified in paragraph (g)(2)(i), (g)(2)(ii), or (g)(2)(iii) of this AD, the inspections required by paragraph (g)(1) of this AD are not required for the repaired area.

(i) Boeing Service Bulletin 737–53–1083, Revision 1, dated October 25, 1985.

(ii) Boeing Service Bulletin 737–53–1083, Revision 2, dated March 25, 1988.

(iii) Boeing Service Bulletin 737–53–1083, Revision 3, dated December 7, 1989.

(3) For Groups 3 and 4 airplanes, as identified in Boeing Special Attention Service Bulletin 737–53–1083, Revision 5, dated July 22, 2014: Accomplishment of a repair specified in Part 3, ''Permanent Repair,'' of Paragraph 3.B., ''Work Instructions,'' of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–53–1083, Revision 5, dated July 22, 2014, except as required by paragraph (j)(2) of this AD, terminates the inspections required by paragraph (g)(1) of this AD for the repaired area(s) only.

(4) For Group 5 airplanes, as identified in Boeing Special Attention Service Bulletin 737–53–1083, Revision 5, dated July 22, 2014: Within 120 days after the effective date of this AD, inspect the forward entry door cutout and airstairs cutout for cracks, and repair any crack, using a method approved in accordance with the procedures specified in paragraph (l) of this AD.

(h) Optional Preventive Modification

For Groups 1 and 2, Configurations 5 and 6 airplanes; and Groups 3 and 4 airplanes; as identified in Boeing Special Attention Service Bulletin 737–53–1083, Revision 5, dated July 22, 2014: Except as required by paragraph (j)(2) of this AD, accomplishment of the preventive modification in accordance with Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–53–1083, Revision 5, dated July 22, 2014, terminates the inspections required by paragraph (g)(1) of this AD.

(i) Post-Modification and Post-Repair Repetitive Inspections

The post-modification and post-repair repetitive inspections specified in table 4 of paragraph 1.E., ''Compliance,'' of Boeing Special Attention Service Bulletin 737–53–1083, Revision 5, dated July 22, 2014, are not required by this AD.

Note 1 to paragraph (i) of this AD: The inspections specified in table 4 of paragraph 1.E., ''Compliance,'' of Boeing Special Attention Service Bulletin 737–53–1083, Revision 5, dated July 22, 2014, may be used in support of compliance with Section 121.1109(c)(2) or 129.109(b)(2) of the Federal Aviation Regulations (14 CFR 121.1109(c)(2) or 14 CFR 129.109(b)(2)). The corresponding actions specified in the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–53–1083, Revision 5, dated July 22, 2014, are not required by this AD.

(j) Exceptions to Service Information Specifications

(1) Where Boeing Special Attention Service Bulletin 737–53–1083, Revision 5, dated July 22, 2014, specifies a compliance time ''after the Revision 4 date of this service bulletin,'' this AD requires compliance within the specified compliance time after the effective date of this AD.

(2) Where Boeing Special Attention Service Bulletin 737–53–1083, Revision 5, dated July 22, 2014, specifies to contact Boeing for repair instructions, this AD requires repair before further flight using a method approved in accordance with the procedures specified in paragraph (l) of this AD.

(k) Credit for Previous Actions

This paragraph provides credit for actions specified in paragraphs (g) and (h) of this AD, if those actions were performed before the effective date of this AD using Boeing Special Attention Service Bulletin 737–53–1083, Revision 4, dated December 18, 2013, which is not incorporated by reference in this AD.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles 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 (m)(1) of this AD. Information may be emailed to: *9-ANM-LAACO-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, Los Angeles 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.

(m) Related Information

(1) For more information about this AD, contact Nenita Odesa, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5234; fax: 562–627–5210; email: *nenita.odesa@faa.gov.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (n)(3) and (n)(4) of this AD.

(n) 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 737–53–1083, Revision 5, dated July 22, 2014.

(ii) Reserved.

(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 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 March 13, 2015.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–06753 Filed 3–27–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 924

[SATS No. MS–024–FOR; Docket No. OSM–2014–0005; S1D1SSS08011000SX066A00067F154S180110; S2D2SSS08011000SX066A00033F15XS501520]

Mississippi Abandoned Mine Land Plan

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are approving an amendment to the Mississippi Abandoned Mine Land Reclamation Plan (hereinafter, the Mississippi Plan) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Mississippi requested concurrence from the Secretary of the Department of the Interior with its certification of completion of all coal-related reclamation objectives. Mississippi intends to request Abandoned Mine Land (AML) Reclamation funds to pursue projects in accordance with section 411 of SMCRA, 30 U.S.C. 1240a.

DATES: Effective March 30, 2015.

FOR FURTHER INFORMATION CONTACT: Sherry Wilson, Director, Birmingham Field Office. Telephone: (205) 290–7282. Email: *swilson@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Mississippi Plan
II. Submission of the Amendment
III. Summary and Disposition of Comments
IV. OSMRE's Decision
V. Procedural Determinations

I. Background on the Mississippi Plan

Title IV of the Act (30 U.S.C. 1231 *et seq.*) established the AML program in order to address the extensive environmental damage caused by past coal mining activities. The AML program is funded primarily by a reclamation fee collected on each ton of coal produced. The money collected is placed in the Abandoned Mine Reclamation Fund (the ''Fund'') and used to finance the reclamation of abandoned coal mines and for other authorized activities. In addition to moneys from the Fund, Title IV also provides for the use of some general Treasury moneys to fund reclamation projects and other authorized activities.

Section 405 of the Act, 30 U.S.C. 1235, allows States and Indian tribes to assume exclusive responsibility for reclamation activity within the State or on Indian lands if they develop and submit to the Secretary of the Interior for approval, a program (often referred to as a plan) for the reclamation of abandoned coal mines. On September 27, 2007, the Secretary of the Interior approved the Mississippi Plan. You can find background information on the Mississippi Plan, including the Secretary's findings, the disposition of comments, and the approval of the plan in the September 27, 2007, **Federal Register** (72 FR 54832). No prior amendments have been made to the Mississippi Plan (30 CFR part 924.20).

II. Submission of the Amendment

By letter dated August 11, 2014 (Administrative Record No. MS–0424), Mississippi certified to OSMRE that all coal-related impacts on abandoned mine lands within the State have been successfully addressed under SMCRA. Mississippi sent the request for concurrence with its certification at its own initiative. As indicated by our November 12, 2014, **Federal Register** (79 FR 67115) notice, we also construed this request for certification as an amendment to Mississippi's Plan. In addition to this current amendment, Mississippi will most likely be required to revise its plan again in the future to implement a program under section 411 of SMCRA.

III. Summary and Disposition of Comments

We announced receipt of the proposed certification in the November 12, 2014, **Federal Register** (79 FR 67115). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the certification's adequacy. We did not receive any requests for a public hearing or meeting and, thus, did not hold one.

Public Comments

The public comment period ended on December 12, 2014. We did not receive any public comments.

Federal Agency Comments

On September 3, 2014, as required by 30 CFR 884.14(a)(2) and 884.15(a), we requested comments on the proposed Mississippi Plan amendment from various Federal agencies with an actual or potential interest in the Mississippi program (Administrative Record No. MS–0424–01). We did not receive any comments.

IV. OSMRE's Decision

After a review of all of the relevant information, on December 18, 2014, the Director of OSMRE, in accordance with section 411(a)(1) of SMCRA (30 U.S.C. 1240(a)(1)) and 30 CFR 875.13(b) determined that Mississippi met all of the applicable criteria and concurred with Mississippi's certification (Administrative Record MS–0424–02). The Director's concurrence with Mississippi's certification of completion of coal reclamation means that Mississippi may now use funds provided under Title IV of SMCRA in accordance with section 411 of SMCRA and its current plan. In addition, as part of its certification and in accordance with 30 CFR 875.13(a)(3), Mississippi agrees to acknowledge and give top priority to any coal-related problem(s) that may be found or occur after submission of the certification.

In order to implement Mississippi's certification, we are amending the Federal regulations at 30 CFR part 924 that codify decisions concerning the Mississippi Plan. Given the technical nature of this rule, we find that delaying the effective date of this rule would be unnecessary and contrary to the public interest. This rule merely codifies the decision by the Director that became immediately effective on December 18, 2014, when he concurred in Mississippi's certification under section 411(a) of SMCRA. Therefore, we find good cause to waive the 30-day delay in effective date under 5 U.S.C. 553(d)(3).

V. Procedural Determinations

Executive Order 12630—Takings

This rule does not have significant takings implications because it is not a governmental action capable of interference with constitutionally protected property rights. A takings implication assessment is not required.

Executive Orders 12866 and 13563—Regulatory Planning and Review

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of Executive Order 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563

emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. This rule is merely a technical amendment to the Mississippi regulations at 30 CFR Part 924 to denote that Mississippi is certified. As such, it does not implicate any of the considerations embodied in this executive order.

Executive Order 12988—Civil Justice Reform

This rule complies with the requirements of Executive Order 12988. Specifically, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Executive Order 13132—Federalism

This rule does not have Federalism implications. It will not have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on federally recognized Indian tribes and have determined that the rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Executive Order 13211—Regulations That Significantly Affect the Supply, Distribution, or Use of Energy

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. This rule is not considered significant under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

We have determined that the revisions in this rule are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act of 1969, as provided in 43 CFR 46.205(b). We have determined the rule is covered by the specific categorical exclusion listed in the Department of the Interior regulations at 43 CFR 46.210(i). That categorical exclusion covers regulations such as this one that are of an administrative or technical nature. We have also determined that the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under the National Environmental Policy Act.

Paperwork Reduction Act

This rule does not contain collections of information that require approval by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior certifies that this rule 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.*). As discussed above, the aggregate economic impact of this rulemaking on small business entities should be minimal.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: (a) Will not have an annual effect on the economy of $100 million; (b) will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act

This rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of $100 million or more in any given year. As previously discussed, this rulemaking will not have a substantial economic impact on any entity.

List of Subjects in 30 CFR Part 924

Intergovernmental relations, Surface mining, Underground mining, Abandoned mine reclamation programs.

Dated: January 20, 2015.

Ervin J. Barchenger,

Regional Director, Mid-Continent Region.

For the reasons set out in the preamble, 30 CFR part 924 is amended as set forth below:

PART 924—MISSISSIPPI

■ 1. The authority citation for Part 924 is revised to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 2. Section 924.25 is added to read as follows:

§ 924.25 Approval of Mississippi abandoned mine land reclamation plan amendments.

The following is a list of the dates on which the State of Mississippi submitted amendments to OSMRE, the dates when the Director's decision approving all, or portions of these amendments, were published in the **Federal Register**, and the State citations or a brief description of each amendment. The amendments in this table are listed in order of the date of final publication in the **Federal Register**.

Original amendment submission date	Date of final publication	Citation/description
August 11, 2014	March 30, 2015	Certification that the State has reclaimed all lands adversely impacted by past coal mining.

[FR Doc. 2015–06958 Filed 3–27–15; 8:45 am]

BILLING CODE 4310–05–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 49

[EPA–R08–OAR–2012–0479; FRL9923–70–Region 8]

Approval and Promulgation of Federal Implementation Plan for Oil and Natural Gas Well Production Facilities; Fort Berthold Indian Reservation (Mandan, Hidatsa and Arikara Nation), North Dakota; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Correcting amendment.

SUMMARY: This document contains corrections to the final rule, which published in the **Federal Register** on March 22, 2013 (78 FR 17836). Errors in the amendatory instruction are identified and corrected in this action.

DATES: This action is effective March 30, 2015.

FOR FURTHER INFORMATION CONTACT: Kathy Ayala, Air Program, U.S. Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129, 303–312–6142, *ayala.kathy@epa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The final regulations for 40 CFR part 49 subsections 49.4161 through 49.4168 that are the subject of this correction were finalized and published March 22, 2013 (78 FR 17836). A previous final rule published in the **Federal Register** at 77 FR 48878, August 15, 2012, published the interim provisions at 40 CFR part 49 subsections 49.140 through 49.147.

Need for Correction

As published, the final regulations contain an error in the amendatory instruction and set-out text:

List of Subjects in 40 CFR Part 49

Environmental protection, Administrative practice and procedure, Air pollution control, Indians, Intergovernmental relations, Reporting and recordkeeping requirements.

Accordingly, 40 CFR part 49 is corrected by making the following correcting amendment:

PART 49—INDIAN COUNTRY: AIR QUALITY PLANNING AND MANAGEMENT

■ 1. The authority citation for Part 49 continues to read as follows:

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

Subpart C—General Federal Implementation Plan Provisions

§§ 49.140 through 49.147 [Removed and Reserved]

■ 2. Remove and reserve §§ 49.140 through 49.147

Dated: March 19, 2015.

Shaun L. McGrath,

Regional Administrator, Region 8.

[FR Doc. 2015–07230 Filed 3–27–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2015–0170; FRL–9925–24–Region 7]

Approval and Promulgation of Implementation Plans; State of Missouri, Control of Sulfur Emissions From Stationary Boilers

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve revisions to the State Implementation Plan (SIP) submitted by the State of Missouri on October 17, 2013, related to amendments to the Missouri rule ''Control of Sulfur Emissions from Stationary Boilers.'' This action provides clarification on the applicability of the provision, and relocates definitions used in the original provision to the ''Definitions and Common Reference Tables'' rule.

DATES: This direct final rule will be effective May 29, 2015, without further notice, unless EPA receives adverse comment by April 29, 2015. If EPA receives adverse comment, we will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2015–0170 by one of the following methods:

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

2. *Email: gonzalez.larry@epa.gov.*

3. *Mail or Hand Delivery:* Larry Gonzalez, 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–2015–0170 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 through *www.regulations.gov* or email information that you consider to be CBI or otherwise protected. 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 docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219. The Regional Office's official hours of business are Monday through Friday, 8:00 to 4:30 excluding legal holidays. 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: Larry Gonzalez, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at 913–551–7041 or by email at *gonzalez.larry@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' or ''our'' refer to EPA. This section provides additional information by addressing the following:

I. What is being addressed in this document?
II. Have the requirements for approval of a SIP revision been met?
III. What Action is EPA taking?

I. What is being addressed in this document?

EPA is taking direct final action to approve revisions to the SIP submitted by the State of Missouri on October 17, 2013, related to Missouri rule 10 CSR 10–5.570 ''Control of Sulfur Emission From Stationary Boilers.'' This action amends 10 CSR 10–5.570 by clarifying that the sulfur dioxide (SO_2) emission limits for breweries specified in subsection (3)(A)2 apply only to the total SO_2 emissions from applicable emission units operating within an installation, and not the combined emissions from the entire brewery. Additionally, definitions originally listed in section (2) of this rule have been removed and are now located at 10 CSR 10–6.020, ''Definitions and Common Reference Tables.''

II. Have the requirements for 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. No public comments were received during the state public comment period. The submission also satisfies 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 taking direct final action to approve this SIP revision. We are publishing this rule without a prior proposed rule because we view this as a noncontroversial action and anticipate no adverse comment. However, in the ''Proposed Rules'' section of this **Federal Register**, we are publishing a separate document that will serve as the proposed rule to approve this SIP revision, if adverse comments are received on this direct final rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. For further information about commenting on this rule, see the **ADDRESSES** section of this document. If EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that this direct final rule will not take effect. We will address all public comments in any subsequent final rule based on the proposed rule.

Statutory and Executive Order Reviews

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of Missouri's rule 10–5.570 ''Control of Sulfur Emission From Stationary Boilers'' described in the direct final 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 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'' under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the 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 May 29, 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. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of this **Federal Register,** rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to

enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: March 17, 2015.

Mark Hague,

Acting Regional Administrator, Region 7.

For the reasons stated in the preamble, EPA amends 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(c) the table is amended by revising the entry for 10–5.570 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 5—Air Quality Regulations and Air Pollution Control Regulations for the St. Louis Metropolitan Area				
*	*	*	*	*
10–5.570	Control of Sulfur Emissions from Stationary Boilers.	10/30/13	3/30/15 *[Insert **Federal Register** citation].*	
*	*	*	*	*

* * * * *

[FR Doc. 2015–07126 Filed 3–27–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2013–0270; FRL–9924–99–Region 4]

Approval and Promulgation of Implementation Plans; Mississippi Infrastructure Requirements for the 2008 Lead National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve in part and disapprove in part the November 17, 2011, State Implementation Plan (SIP) submission, provided by the Mississippi Department of Environmental Quality (MDEQ) for inclusion into the Mississippi SIP. This final action pertains to the Clean Air Act (CAA or the Act) infrastructure requirements for the 2008 Lead national ambient air quality standards (NAAQS). The CAA requires that each state adopt and submit a SIP for the implementation, maintenance, and enforcement of each NAAQS promulgated by EPA, which is commonly referred to as an ''infrastructure'' SIP. MDEQ certified that the Mississippi SIP contains provisions that ensure the 2008 Lead NAAQS is implemented, enforced, and maintained in Mississippi. With the exception of provisions pertaining to prevention of significant deterioration (PSD) permitting, for which EPA is not acting upon, and disapproving certain state boards requirements, EPA is taking final action to approve Mississippi's infrastructure SIP submission, provided to EPA on November 17, 2011, because it addresses the required infrastructure elements for the 2008 Lead NAAQS.

DATES: This rule will be effective April 29, 2015.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2013–0270. 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, i.e., Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section (formerly the Regulatory Development Section), Air Planning and Implementation Branch (formerly the Air Planning Branch), Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Zuri Farngalo, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9152. Mr. Farngalo can be reached via electronic mail at *farngalo.zuri@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Upon promulgation of a new or revised NAAQS, sections 110(a)(1) and (2) of the CAA require states to address basic SIP requirements, including emissions inventories, monitoring, and modeling to assure attainment and maintenance for that new NAAQS. Section 110(a) of the CAA generally requires states to make a SIP submission to meet applicable requirements in order to provide for the implementation, maintenance, and enforcement of a new or revised NAAQS within three years following the promulgation of such NAAQS, or within such shorter period as EPA may prescribe. These SIP submissions are commonly referred to as ''infrastructure'' SIP submissions. Section 110(a) imposes the obligation upon states to make an infrastructure SIP submission to EPA for a new or revised NAAQS, but the contents of that submission may vary depending upon the facts and circumstances. In particular, the data and analytical tools available at the time the state develops and submits the infrastructure SIP for a new or revised NAAQS affect the content of the submission. The contents of such infrastructure SIP submissions may also vary depending upon what provisions the state's existing SIP already contains. In the case of the 2008 Lead NAAQS, states typically have met the basic program elements required in section 110(a)(2) through earlier SIP submissions in connection with previous lead NAAQS.

More specifically, section 110(a)(1) provides the procedural and timing requirements for SIPs. Section 110(a)(2) lists specific elements that states must meet for infrastructure SIP requirements related to a newly established or revised NAAQS. As mentioned above, these requirements include basic structural SIP elements such as modeling, monitoring, and emissions inventories that are designed to assure attainment and maintenance of the NAAQS. The applicable infrastructure SIP requirements that are the subject of this rulemaking are listed below.[1]

- 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, prevention of significant deterioration (PSD) and new source review (NSR).[2]
- 110(a)(2)(D): Interstate and international transport provisions.
- 110(a)(2)(E): Adequate personnel, funding, and authority.
- 110(a)(2)(F): Stationary source monitoring and reporting.
- 110(a)(2)(G): Emergency episodes.
- 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.

On November 18, 2014, EPA proposed to approve Mississippi's November 17, 2011, 2008 Lead NAAQS infrastructure SIP submission with the exception of provisions pertaining to PSD permitting in sections 110(a)(2)(C), prong 3 of D(i) and (J) and the majority requirements respecting significant portion of income for state boards of section 110(a)(2)(E)(ii). EPA proposed disapproval of the majority requirements respecting significant portion of income for state boards of section 110(a)(2)(E)(ii). EPA will address the PSD permitting requirements in sections 110(a)(2)(C), prong 3 of D(i) and (J) in a separate action. *See* 79 FR 68648.

II. Today's Action

In this rulemaking, EPA is taking final action to approve Mississippi's infrastructure submission as demonstrating that the State meets the applicable requirements of sections 110(a)(1) and (2) of the CAA for the 2008 Lead NAAQS, with the exception of PSD permitting provisions in sections 110(a)(2)(C), prong 3 of D(i) and (J). EPA will be taking action on these elements in a separate action. Additionally, EPA is disapproving Mississippi's infrastructure submission with regard to the majority requirements respecting significant portion of income for state boards in section 110(a)(2)(E)(ii).

III. Final Action

With the exception of provisions pertaining to PSD permitting requirements in sections 110(a)(2)(C), prong 3 of D(i) and (J) and the majority requirements respecting significant portion of income for state boards of section 110(a)(2)(E)(ii), EPA is taking final action to approve Mississippi's November 17, 2011, infrastructure submission because it addresses the required infrastructure elements for the 2008 Lead NAAQS. EPA is disapproving in part section 110(a)(2)(E)(ii) because a majority of board members that approve permits or enforcement orders in Mississippi may still derive a significant portion of income from persons subject to permits or enforcement orders issued by such Mississippi Boards, therefore, its current SIP does not meet the section 128(a)(1) majority requirements respecting significant portion of income. With the exceptions noted above MDEQ has addressed the elements of the CAA 110(a)(1) and (2) SIP requirements pursuant to section 110 of the CAA to ensure that the 2008 Lead NAAQS is implemented, enforced, and maintained in Mississippi.

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 Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

[1] 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 the nonattainment area plan requirements are due pursuant to other provisions of the CAA for submission of SIP revisions specifically applicable for attainment planning purposes. 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. Today's proposed rulemaking does not address infrastructure elements related to section 110(a)(2)(I) or the nonattainment planning requirements of 110(a)(2)(C).

[2] This rulemaking only addresses requirements for this element as they relate to attainment areas.

• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

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

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

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

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 29, 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, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: March 11, 2015.

Heather McTeer Toney,

Regional Administrator, Region 4.

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 Z—Mississippi

■ 2. Section 52.1270(e) is amended by adding a new entry ''110(a)(1) and (2) Infrastructure Requirements for the 2008 Lead National Ambient Air Quality Standards'' at the end of the table to read as follows:

§ 52.1270 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED MISSISSIPPI NON-REGULATORY PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approval date	Explanation
*	*	*	*	*
110(a)(1) and (2) Infrastructure Requirements for the 2008 Lead National Ambient Air Quality Standards 110(a)(2)(E)(ii) Infrastructure Requirement for 2008 Lead National Ambient Air Quality Standards.	11/4/2011	3/30/15	[Insert citation of publication].	With the exception of provisions pertaining to PSD permitting requirements in sections 110(a)(2)(C), prong 3 of D(i) and (J) and the majority of requirements respecting significant portion of income of section 110(a)(2)(E)(ii) (related to section 128(a)(2)).

■ 3. Section 52.1272 is amended by adding paragraph (c) to read as follows:

§ 52.1272 Approval status.

* * * * *

(c) *Disapproval.* With respect to the significant portion of income requirement of section 128(a)(1), the provisions included in the October 11, 2012, infrastructure SIP submission did not preclude at least a majority of the members of the Mississippi Board from receiving a significant portion of their income from persons subject to permits or enforcement orders issued by the Mississippi Boards. Because a majority of board members may still derive a significant portion of income from persons subject to permits or enforcement orders issued by the Mississippi Boards, the Mississippi SIP does not meet the section 128(a)(1) majority requirements respecting significant portion of income, and as such, EPA is today proposing to disapprove the State's 110(a)(2)(E)(ii) submission as it relates only to this portion of section 128(a)(1).

[FR Doc. 2015–06765 Filed 3–27–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2015–0636; FRL–9922–77–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Revision to Allegheny County Rules; Preconstruction Permit Requirements—Nonattainment; New Source Review

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is granting full approval of a revision to the Commonwealth of Pennsylvania State Implementation Plan (SIP), submitted on June 25, 2012 (June 2012 SIP submittal) by the Pennsylvania Department of Environmental Protection (PADEP) on behalf of the Allegheny County Health Department (ACHD) as amended by PADEP in letters dated February 20, 2013 and June 27, 2014. The SIP revision pertains to ACHD's Nonattainment New Source Review (NNSR) preconstruction permitting regulations which incorporate by reference Pennsylvania's NNSR provisions. This action is being taken under the Clean Air Act.

DATES: This rule is effective on April 29, 2015.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2015–0636. 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, and 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Pennsylvania Department of Environmental Protection, Bureau of Air Quality Control, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105; and Allegheny County Health Department, Bureau of Environmental Quality, Division of Air Quality, 301 39th Street, Pittsburgh, Pennsylvania 15201.

FOR FURTHER INFORMATION CONTACT: Paul Wentworth, (215) 814–2183, or by email at *wentworth.paul@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Summary of SIP Revision

On December 17, 2014 (79 FR 75104), EPA published a notice of proposed rulemaking (NPR) for the Commonwealth of Pennsylvania. The NPR proposed full approval of the June 2012 SIP submittal which included revisions to the ACHD's NNSR program contained in the Pennsylvania SIP. The revisions to ACHD's NNSR program include ACHD's Article XXI which incorporates by reference Pennsylvania's NNSR provisions at 25 Pa. Code 127.201–127.217. The June 2012 SIP submittal also includes other changes to ACHD's NNSR program including changes to regulatory definitions and text, deletions of certain provisions, reordered paragraphs, and inclusion of plantwide applicability limit requirements.

ACHD amended the ACHD NNSR regulations at Article XXI, sections 2101 and 2102, to meet the requirements of 40 CFR 51.165. This approval action replaces the previous version of Article XXI which was approved into the Pennsylvania SIP on November 14, 2002. *See* 67 FR 68935.

The June 2012 SIP submittal includes amendments to the following sections of ACHD's Rules and Regulations, Article XXI: section 2101.20 (Definitions); section 2102.04 (Installation permits); section 2102.06 (Major Sources Locating in or Impacting a Nonattainment Area); and section 2102.08 (Emissions Offset Registration). After the June 2012 SIP submittal, PADEP had provided two letters clarifying the June 2012 SIP submittal. In a letter dated February 20, 2013, PADEP stated it had inadvertently redacted via strike out certain regulatory text from one provision in an ACHD regulation submitted for SIP approval in the June 2012 SIP submittal. PADEP accidentally deleted language at the end of subsection (f) of ACHD's Rules and Regulations, Article XXI, section 2102.06(f) (Requirements for Modeling). The February 20, 2013 PADEP letter requested EPA to include the full text of Article XXI, section 2102.06(f) for the revised Pennsylvania SIP including the text inadvertently deleted in the June 2012 SIP submission.[1]

In a second letter from PADEP dated June 27, 2014, PADEP modified the June 2012 SIP submittal and withdrew from its SIP submittal specific language from an ACHD regulation included in the June 2012 SIP submittal. The regulatory text PADEP withdrew from our consideration for inclusion in the Pennsylvania SIP was regulatory text in ACHD's Rules and Regulations, Article XXI, section 2102.06(b)(1), (b)(3)(a), (e), and (g) which provided a process for automatically incorporating additions, revisions, or deletions from Pennsylvania's NNSR regulations into ACHD's SIP effective on the date of revision to Pennsylvania's NNSR regulations.[2] *See* 79 FR 75104 (discussing withdrawn text language). As a result of PADEP's June 27, 2014 letter, the language withdrawn by Pennsylvania from the June 2012 SIP submittal is not part of this rulemaking action. However, as a result of PADEP's February 20, 2013 letter, the inadvertently redacted language from ACHD's Rules and Regulations, Article XXI, section 2102.06(f) is part of this rulemaking language.

EPA's November 17, 2014 technical support document (TSD) explains in detail the revisions to the Pennsylvania SIP contained in the Commonwealth's June 2012 SIP submittal. The TSD is included in the docket for this rulemaking action and is available online at *www.regulations.gov.* The TSD also explains in detail the language withdrawn from ACHD's Article XXI, section 2102.06, includes EPA's analysis of the June 2012 SIP submittal, and provides support for the proposed and final actions on the submittal. Because ACHD incorporated by reference Pennsylvania's SIP approved NNSR regulations into ACHD's NNSR regulations, EPA stated in the NPR there was no need to re-evaluate the same NNSR elements EPA had already approved for the Pennsylvania SIP on May 14, 2012. As discussed in the NPR and in the TSD, the June 2012 SIP submittal includes revisions to ACHD's NNSR program which are consistent with the CAA, with currently promulgated Federal NNSR regulations, and with NNSR regulations which EPA has previously approved into Pennsylvania's SIP.

The NPR and TSD contain detailed discussions of the Pennsylvania SIP submission for Allegheny County and EPA's rationale for approving the June 2012 SIP submittal which addresses NNSR requirements in the CAA and its implementing regulations in 40 CFR 51.165 applicable as of the time of the June 2012 SIP submittal. Therefore, those discussions will not be restated

[1] For the Pennsylvania SIP, ACHD's Article XXI, section 2102.06(f) (Requirements for Modeling) should read as follows: ''Where air quality models are used to meet the provisions of this section, modeling shall be based on the applicable models and other requirements specified in 40 CFR part 51 Appendix W (Guideline on Air Quality Models). Where an air quality model is inappropriate, the model may be modified or another model may be substituted only on a case-by-case basis at the Department's discretion upon written approval by the administrator of EPA. In addition, use of a modified or substituted model must be subject to notice and opportunity for public comment under procedures set forth in 40 CFR 51.102.''

[2] The language excluded from the Pennsylvania SIP from ACHD's Rules and Regulations, Article XXI, section 2102.06(b)(1), (b)(3)(a), (e), and (g) is the following language ''[a]dditions, revisions, or deletions to such regulations by the Commonwealth are incorporated in this Subsection and are effective on the date established by the state regulation, unless otherwise established by regulation under this Article.''

here. No comments were received on the NPR.

II. Final Action

EPA is approving as a revision to the Pennsylvania SIP the Commonwealth's June 2012 SIP submittal, as amended by PADEP in letters dated February 20, 2013 and June 27, 2014, which includes ACHD's NNSR regulations at Article XXI, sections 2101 and 2102.

III. Incorporation by Reference

In this rulemaking action, the EPA is finalizing regulatory text proposing to include in a final rule that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the ACHD regulations at Article XXI, sections 2101 and 2102 regarding Nonattainment New Source Review permitting requirements for Allegheny County. The EPA has made and will continue to make, these documents generally available through *www.regulations.gov* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

A. General Requirements

Under the CAA, the Administrator is required to approve a SIP submission thaIt complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely 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).

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 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 rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule 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 Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 29, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule 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).) This final rule approves Allegheny County's nonattainment new source review (NNSR) preconstruction air quality permit program.

List of Subjects in 40 CFR Part 52

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

Dated: March 13, 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 NN—Pennsylvania

■ 2. In § 52.2020, the table in paragraph (c)(2) is amended by:

■ a. Under Part A, revising the 7th entry for ''2101.20''; and

■ b. Under Part B, revising the entries for ''2102.04'', ''2102.06'', ''2102.08.''

§ 52.2020 Identification of plan.

* * * * *

(c) * * *

(2) * * *

Article XX or XXI citation	Title/subject	State effective date	EPA approval date	Additional explanation/§ 52.2063 citation
*	*	*	*	*
Part A—General				

Article XX or XXI citation	Title/subject	State effective date	EPA approval date	Additional explanation/§ 52.2063 citation
*	*	*	*	*
2101.20	Definitions	4/3/2012	3/30/2015 [Insert **Federal Register** citation].	Revise the latest entry dated 11/26/14, 79 FR 70471 by revising the existing definition of "Major Source" and "Major Modification".
*	*	*	*	*
Part B—Permits Generally				
*	*	*	*	*
2102.04	Permits Generally	4/3/2012	3/30/2015 [Insert **Federal Register** citation].	
*	*	*	*	*
2102.06	Major Sources Locating in or Impacting a Nonattainment Area.	4/3/2012	3/30/2015 [Insert **Federal Register** citation].	As per request by PADEP in a letter to EPA dated June 27, 2014, the following language appearing at paragraph b.1; subparagraph b.3.A; and Subsections e and g, is excluded from the SIP: "Additions, revisions, or deletions to such regulations by the Commonwealth are incorporated in this Subsection and are effective on the date established by the state regulation, unless otherwise established by regulation under this Article." As per letter from PADEP dated 2/20/2013, the June 25, 2012 SIP submission inadvertently deleted language from the end of subsection (f) of the regulation submitted with SIP submittal. The SIP revision incorporating Article XXI § 2102.06(f) should read as follows "f. Requirements for Modeling. Where air quality models are used to meet the provisions of this section, modeling shall be based on the applicable models and other requirements specified in 40 CFR Part 51 Appendix W (Guideline on Air Quality Models). Where an air quality model is inappropriate, the model may be modified or another model may be substituted only on a case-by-case basis at the Department's discretion upon written approval by the administrator of EPA. In addition, use of a modified or substituted model must be subject to notice and opportunity for public comment under procedures set forth in 40 CFR 51.102."
*	*	*	*	*
2102.08	Emission Offset Registration.	4/3/2012	3/30/2015 [Insert **Federal Register** citation].	
*	*	*	*	*

* * * * *

[FR Doc. 2015–07106 Filed 3–27–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2012–0352; FRL–9925–51–Region 8]

Approval and Promulgation of Air Quality Implementation Plans; State of Montana Second 10-Year Carbon Monoxide Maintenance Plan for Billings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a State Implementation Plan (SIP) revision submitted by the State of Montana. On July 13, 2011, the Governor of Montana's designee submitted to EPA a second 10-year maintenance plan for the Billings area for the carbon monoxide (CO) National Ambient Air Quality Standard (NAAQS). This maintenance plan addresses maintenance of the CO NAAQS for a second 10-year period beyond the original redesignation. EPA

is also approving an alternative monitoring strategy for the Billings CO maintenance area, which was submitted by the Governor's designee on June 22, 2012.

DATES: This final rule is effective April 29, 2015.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R08–OAR–2012–0352. 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 St., 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: Adam Clark, EPA, Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129, (303) 312–7104, *clark.adam@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 *CO* mean or refer to carbon monoxide.

(iii) The words *EPA, we, us* or *our* mean or refer to the United States Environmental Protection Agency.

(iv) The initials *NAAQS* mean or refer to the National Ambient Air Quality Standards.

(v) The initials *SIP* mean or refer to State Implementation Plan.

(vi) The words *Montana* and *State* mean or refer to the State of Montana.

I. Background

Eight years after an area is redesignated to attainment, Clean Air Act (CAA) section 175A(b) requires the state to submit a subsequent maintenance plan to EPA, covering a second 10-year period.[1] This maintenance plan must demonstrate continued compliance with the NAAQS during this second 10-year period. On July 13, 2011, the Governor of Montana's designee submitted to EPA a second 10-year maintenance plan for the Billings area for the CO NAAQS.

Along with the revised Billings Maintenance Plan, the State submitted a CO maintenance plan for the Great Falls, Montana maintenance area, and an alternative strategy for monitoring continued attainment of the CO NAAQS in all of the State's CO maintenance areas on July 13, 2011.[2] The State submitted the alternative monitoring strategy in order to conserve resources by discontinuing the gaseous CO ambient monitors in both the Billings and Great Falls CO maintenance areas. We commented on the State's ''Alternative Monitoring Strategy,'' and the State submitted a revised version of the strategy, which incorporated our comments on June 22, 2012.

In a document published on December 2, 2014, we proposed approval of the Billings second 10-year maintenance plan and the associated ''Alternative Monitoring Strategy.'' (79 FR 71369)

II. Response to Comments

The comment period for our December 2, 2014 proposed rule was open for 30 days. We did not receive any comments on the proposed action.

III. Final Action

EPA is approving the revised Billings Maintenance Plan submitted on July 13, 2011. This maintenance plan meets the applicable CAA requirements and EPA has determined it is sufficient to provide for maintenance of the CO NAAQS over the course of the second 10-year maintenance period out to 2022.

EPA is also approving the State's Alternative Monitoring Strategy, submitted on June 22, 2012, for the Billings CO maintenance area. We are not approving application of the Alternative Monitoring Strategy in other areas of Montana with this action, as the Alternative Monitoring Strategy must be considered on a case-by-case basis specific to the circumstances of each particular CO maintenance area rather than broadly.

[1] In this case, the initial maintenance period extended through 2012. Thus, the second 10-year period extends through 2022.

[2] In addition to Billings and Great Falls, the Missoula, MT CO maintenance area was included in the July 13, 2011 Alternative Monitoring Strategy.

IV. Statutory and Executive Orders Review

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

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

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have

tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 29, 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, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

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

Dated: March 17, 2015.

Debra H. Thomas,

Acting Regional Administrator, Region 8.

40 CFR part 52 is amended to read 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 BB—Montana

■ 2. Section 52.1373 is amended by revising paragraph (b) to read as follows:

§ 52.1373 Control strategy: Carbon monoxide.

* * * * *

(b) Revisions to the Montana State Implementation Plan, revised Carbon Monoxide Maintenance Plan for Billings, as submitted by the Governor's Designee on July 13, 2011, and the associated Alternative Monitoring Strategy for Billings, as submitted by the Governor's Designee on June 22, 2012.

* * * * *

[FR Doc. 2015–07227 Filed 3–27–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2015–0033; FRL–9925–19–Region 6]

Approval and Promulgation of Implementation Plans; Texas; Public Participation for Air Quality Permit Applications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking a direct final action to approve two provisions submitted by the State of Texas as revisions to the Texas State Implementation Plan (SIP) on July 2, 2010, specific to the applicability of the public notice requirements to applications for Plant-Wide Applicability (PAL) permits and standard permits for concrete batch plants without enhanced controls. Today's direct final action will complete the rulemaking process started in our December 13, 2012, proposal and approve the public notice provisions into the Texas SIP. The EPA is also taking direct final action to convert the public notice applicability provisions for Texas Flexible Permits from a final conditional approval to a full approval. The EPA is taking this action under section 110 and parts C and D of the Clean Air Act (CAA or the Act).

DATES: This rule is effective on May 29, 2015 without further notice, unless the EPA receives relevant adverse comments by April 29, 2015. If the EPA receives such comments, the EPA will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket No. EPA–R06–OAR–2015–0033, by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions.
- Email: Adina Wiley at *wiley.adin&*
- Mail or delivery: Ms. Adina Wiley, Air Permits Section (6PD–R), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733.

Instructions: Direct your comments to Docket ID No. EPA–R06–OAR–2015–0033. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Do not submit information through *http://www.regulations.gov* or email, if you believe that it is CBI or otherwise protected from disclosure. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means that the 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 the EPA without going through *http://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, the EPA recommends that you include your name and other contact information in the body of your comment along with any disk or CD–ROM submitted. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters and any form of encryption and should be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: The index to the docket for this action is available electronically at *www.regulations.gov* and in hard copy at EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available at either location (*e.g.,* CBI).

FOR FURTHER INFORMATION CONTACT: Ms. Adina Wiley, 214–665–2115,

wiley.adina@epa.gov. To inspect the hard copy materials, please schedule an appointment with Ms. Adina Wiley or Mr. Bill Deese at 214–665–7253.

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

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I. Background

The Clean Air Act at section 110(a)(2)(C) requires States to develop and implement permitting programs for attainment and nonattainment areas that cover both construction and modification of stationary sources. The EPA codified minimum requirements for these State permitting programs including public participation and notification requirements at 40 CFR 51.160—51.164.

On June 2, 2010, the Texas Commission on Environmental Quality (TCEQ) adopted amendments to 30 TAC Chapter 39, Public Notice; Chapter 55, Requests for Reconsideration and Contested Case Hearings; Public Comment; and Chapter 116, Control of Air Pollution by Permits for New Construction or Modification; and corresponding revisions to the Texas SIP. Chairman Bryan W. Shaw, Ph.D., submitted these amendments to the EPA for approval as revisions to the Texas SIP in a letter dated July 2, 2010.

The EPA has taken final action on the majority of the July 2, 2010, SIP submittal for public notice. But, through inadvertent errors, we have neglected to complete the rulemaking process for the public notice applicability provisions for applications for PAL permits at 30 TAC section 39.402(a)(8), standard permits for concrete batch plants without enhanced controls at 30 TAC section 39.402(a)(11), and new and amended flexible permits at 30 TAC section 39.402(a)(4) and (a)(5).

II. The EPA's Evaluation

A. Public Notice Applicability for Applications for PALs and Standard Permits for Concrete Batch Plants Without Enhanced Controls

The EPA proposed approval of the majority of the July 2, 2010, Texas SIP submittal on December 13, 2012, at 77 FR 74129. In this proposed rulemaking and our accompanying Technical Support Document, the EPA presented our evaluation and preliminary determination for the applicability of the public notice requirements for applications for PAL permits at 30 TAC 39.402(a)(8) and standard permits for concrete batch plants without enhanced controls at 30 TAC 39.402(a)(11). In both instances, we determined that the public notice provisions in Chapter 39 for each type of permit application were consistent with all applicable federal requirements and would be fully approvable into the Texas SIP. However, we neglected to include the specific provisions at 30 TAC 39.402(a)(8) and 39.402(a)(11) in our ''Proposed Action'' statement in the December 13, 2012, **Federal Register** document. While the public had the opportunity to review and comment on our evaluation and preliminary determination of approvability of these provisions, we never formally proposed these provisions for approval into the Texas SIP. As such, we did not finalize approval of 30 TAC 39.402(a)(8) and (a)(11) with the majority of the public notice provisions on January 6, 2014 at 79 FR 551.

Please see the EPA's December 13, 2012, proposed approval at 77 FR 74129 for our technical evaluation. The evaluation of the applicability of the public notice provisions for PAL permit applications can be found at page 74136. The evaluation of the applicability of the public notice provisions for permit applications for standard permits for concrete batch plants can be found at pages 74136–74140. The Technical Support Document dated December 12, 2012, available in the rulemaking docket for this action, provides additional details to support our determination that the public notice applicability provisions at 30 TAC 39.402(a)(8) and (a)(11) are consistent with federal requirements and fully approvable into the Texas SIP. We incorporate our previous evaluation of these two provisions into this action. We note that because the evaluation was included in our previous preamble and TSD, we did accept and respond to any comments received regarding the applicability of public notice provisions for applications for PALs and standard permits for concrete batch plants without enhanced controls. The EPA received and responded to comments about PAL public notice, but none specific to the applicability provision at 30 TAC section 39.402(a)(8). See 79 FR 551, at 556 and 557–558. Our evaluation and preliminary determination of approvability did not change as a result of these comments. The EPA did not receive any comments specific to the applicability of the public notice provisions for standard permits for concrete batch plants without enhanced controls at 30 TAC 39.402(a)(11); therefore our evaluation of that provision also remains unchanged.

Today's final action is merely correcting our previous error in failing to propose and finalize incorporation of these two provisions into the SIP on the basis of our previous technical evaluation and preliminary determination. The EPA has not changed our rationale. We continue to believe that 30 TAC 39.402(a)(8) and (a)(11) are fully approvable and it is our intent to include these provisions in the Texas SIP.

B. Public Notice Applicability for Applications for New and Amended Flexible Permits

The EPA finalized a conditional approval of the Texas Flexible Permits Program on July 14, 2014, at 79 FR 40666. Our final action included conditional approval of the public notice applicability provisions for applications for new and amended flexible permits at 30 TAC sections 39.402(a)(4) and (a)(5) as submitted on July 2, 2010. As a result of this action, the public notice provisions at 30 TAC sections 39.402(a)(4) and (a)(5) became a part of the Texas SIP contingent upon the TCEQ satisfying the conditions of the December 9, 2013, commitment letter.[1]

In a subsequent proposed rulemaking on December 31, 2014, the EPA determined that the TCEQ satisfied all commitments from the December 9, 2013, commitment letter and thus we proposed to convert our final conditional approval of the Texas Flexible Permits Program to a full approval. See 79 FR 78752. However, we neglected to include the public notice applicability provisions at 30 TAC section 39.402(a)(4) and (a)(5) in that proposal.

Today's final action is merely correcting our previous error in failing to include the public notice applicability provisions for Flexible Permits in our December 2014 proposal to convert the conditional approval to a full approval. Because the EPA has determined that the TCEQ satisfied all

[1] The December 9, 2013, commitment letter required changes to the Flexible Permits Program in 30 TAC Chapter 116, but did not require any changes to the public notice requirements for new and amended flexible permits at 30 TAC sections 39.402(a)(4) and (a)(5).

commitments from the December 9, 2013, commitment letter, the public notice provisions for the Texas Flexible Permit program at 30 TAC sections 39.402(a)(4) and (a)(5) should be converted to a full approval. The conversion of the remainder of the conditionally approved Texas Flexible Permit program to a full approval will be addressed in a separate rulemaking.

III. Final Action

We are approving through a direct final action revisions to the Texas SIP that pertain to the applicability of public notice provisions for PAL permit applications at 30 TAC section 39.402(a)(8) and for applications for standard permits for concrete batch plants without enhanced controls at 30 TAC section 39.402(a)(11). The EPA has determined that these two provisions are consistent with all applicable federal requirements for public notice requirements for PAL permit applications and minor NSR. Therefore, we are approving 30 TAC sections 39.402(a)(8) and 39.402(a)(11) into the Texas SIP as submitted on July 2, 2010. In today's direct final action, the EPA is also converting our final conditional approval to a final full approval for the applicability of public notice provisions for applications for new and amended flexible permits at 30 TAC sections 39.402(a)(4) and (a)(5). The EPA is publishing this rule without prior proposal because we view this as a non-controversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the SIP revision if relevant adverse comments are received.

Today's direct final rule will be effective on May 29, 2015 without further notice unless we receive relevant adverse comment by April 29, 2015.

If we receive relevant adverse comments, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. We will address those public comments in a subsequent final rule based on the proposed rule. Any parties interested in commenting must do so at this time. The EPA will not institute a second comment period on this action. Please note that if we receive relevant adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of revisions to the Texas regulations concerning the applicability of public notice requirements as described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents generally available electronically through *http://www.regulations.gov* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

V. Statutory and Executive Order Reviews

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 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 the 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. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. 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 May 29, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule 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, Carbon monoxide, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate Matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: March 16, 2015.

Samuel Coleman,

Acting Regional Administrator, Region 6.

Therefore, 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart SS—Texas

■ 2. In § 52.2270, the table in paragraph (c) is amended by revising the entry ''Section 39.402'' to read as follows:

§ 52.2270 Identification of plan.

* * * * *

(c) * * *

EPA APPROVED REGULATIONS IN THE TEXAS SIP

State citation	Title/subject	State approval/ submittal date	EPA approval date	Explanation
*	*	*	*	*
Chapter 39—Public Notice				
Subchapter H—Applicability and General Provisions				
Section 39.402	Applicability to Air Quality Permits and Permit Amendments.	6/2/2012	3/30/2015 *[Insert Federal Register citation].*	SIP includes 39.402(a)(1)–(a)(6), (a)(8), and (a)(11).
*	*	*	*	*

* * * * *

[FR Doc. 2015–07124 Filed 3–27–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 711

[EPA–HQ–OPPT–2014–0809; FRL–9924–84]

RIN 2070–AK01

Withdrawal of Partial Exemption for Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In the **Federal Register** issue of January 27, 2015, EPA published a direct final rule that amended the list of chemical substances that are partially exempt from reporting additional information under the Chemical Data Reporting (CDR) rule to add certain chemical substances. EPA received an adverse comment pertinent to all six of the chemical substances that are the subject of that rule. This document accordingly withdraws the direct final rule.

DATES: This rule is effective March 30, 2015.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Loraine Passe, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–9064; email address: *passe.loraine@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What rule is being withdrawn?

In the January 27, 2015 **Federal Register** (80 FR 4482) (FRL–9921–56), EPA added certain chemical substances to the list of chemical substances that are partially exempt from reporting additional information under the Chemical Data Reporting (CDR) rule. EPA later received an adverse comment that is pertinent to all six of the chemical substances that are the subject of that rule (EPA–HQ–OPPT–2014–0809). In accordance with the procedures described in the January 27, 2015 **Federal Register** document, EPA is withdrawing the direct final rule. EPA anticipates that it will publish, in the near future, a notice proposing to add these six chemical substances to the list of chemical substances that are partially exempt from reporting additional information under the Chemical Data Reporting (CDR) rule.

II. How do I access the docket?

To access the docket, please go to *http://www.regulations.gov* and follow the online instructions using the docket ID number EPA–HQ–OPPT–2014–0809. Additional information about the Docket Facility is also provided under **ADDRESSES** in the January 27, 2015 **Federal Register** document. If you have questions, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

III. Statutory and Executive Order Reviews

The reviews discussed in the January 27, 2015 **Federal Register** document are not applicable to this final rule because it is simply a withdrawal.

IV. Congressional Review Act (CRA)

Pursuant to the CRA, 5 U.S.C. 801 *et seq.,* EPA will submit a report containing this rule amendment 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 action in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 711

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements, Administrative practice and procedure.

Dated: March 20, 2015.

James Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, 40 CFR chapter I is amended as follows:

PART 711—TSCA CHEMICAL DATA REPORTING REQUIREMENTS

■ 1. The authority citation for part 711 continues to read as follows:

Authority: 15 U.S.C. 2607(a).

■ 2. In § 711.6, in Table 2 of paragraph (b)(2)(iv), the following CASRN numbers are removed as set forth below.

§ 711.6 Chemical substances for which information is not required.

* * * * *

(b) * * *

(2) * * *

(iv) * * *

TABLE 2—CASRN OF PARTIALLY EXEMPT CHEMICAL SUBSTANCES

CASRN	Chemical
* * *	* * * * *
61788–61–2	Fatty acids, tallow, Me esters.
* * *	* * * * *
67762–26–9	Fatty acids, C14–18 and C16–18-unsatd., Me esters.
67762–38–3	Fatty acids, C16–18 and C–18-unsatd., Me esters.
67784–80–9	Soybean oil, Me esters.
* * *	* * * * *
129828–16–6	Fatty acids, canola oil, Me esters
515152–40–6.	Fatty acids, corn oil, Me esters.
* * *	* * * * *

[FR Doc. 2015–06933 Filed 3–27–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 3160

[LLWO300000 L13100000.PP0000 14X]

RIN 1004–AE26

Oil and Gas; Hydraulic Fracturing on Federal and Indian Lands

Correction

In rule document 2015–06658, appearing on pages 16128–16222, in the Issue of March 26, 2015, make the following corrections:

§ 3162.3–3 Subsequent well operations; Hydraulic fracturing. [Corrected]

1. On page 16218, in § 3162.3–3 (a)(5), in the table in the first column, in the fifth row, the entry ''(5) Authorized drilling operations were completed after September 22, 2015.'' should read ''(5) Authorized drilling operations were completed after December 26, 2014.''

2. On the same page, in § 3162.3–3, in the same table, in the first column, in the sixth row, the entry ''(6) Authorized drilling activities were completed before September 22, 2015'' should read ''(6) Authorized drilling activities were completed before December 26, 2014.''

[FR Doc. C1–2015–06658 Filed 3–26–15; 4:15 pm]

BILLING CODE 1505–01–D

OFFICE OF PERSONNEL MANAGEMENT

45 CFR Part 800

RIN 3206–AN12

Patient Protection and Affordable Care Act; Establishment of the Multi-State Plan Program for the Affordable Insurance Exchanges; Correction

AGENCY: Office of Personnel Management.

ACTION: Final rule; correction.

SUMMARY: The Office of Personnel Management (OPM) is correcting a final rule that appeared in the **Federal Register** of February 24, 2015 (80 FR 9649). The document implementing modifications to the Multi-State Plan (MSP) Program based on the experience of the Program to date.

DATES: Effective March 26, 2015.

FOR FURTHER INFORMATION CONTACT: Cameron Stokes by telephone at (202) 606–2128, by FAX at (202) 606–4430, or by email at *mspp@opm.gov.*

SUPPLEMENTARY INFORMATION: In FR Doc. 2015–03421, appearing on page 9649 in the **Federal Register** of Tuesday, February 24, 2015, the following corrections are made:

1. On page 9655, in the third column, the heading ''List of Subjects in 5 CFR part 800'' is revised to read, ''List of Subjects in 45 CFR part 800.''

2. On page 9655, in the third column, the last paragraph should be revised to read:

''Accordingly, the U.S. Office of Personnel Management is revising part 800 to title 45, Code of Federal Regulations, to read as follows:''

U.S. Office of Personnel Management.

Steve Hickman,

Regulatory Affairs, Office of the Executive Secretariat.

[FR Doc. 2015–07330 Filed 3–26–15; 4:15 pm]

BILLING CODE 6325–64–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Part 1340

Technical Regulation: Removal of Child Abuse and Neglect Prevention and Treatment Act Implementing Regulations

AGENCY: Children's Bureau, Administration on Children, Youth and Families, Administration for Children and Families, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Administration for Children and Families is removing the Child Abuse Prevention and Treatment Act (CAPTA) regulations in their entirety. These regulations no longer apply to the CAPTA programs they were originally designed to implement because of major legislative changes to CAPTA since the regulations were issued.

DATES: This rule is effective June 29, 2015.

FOR FURTHER INFORMATION CONTACT: Kathleen McHugh, Director of Policy, Children's Bureau, Administration on Children, Youth and Families, (202) 401–5789 or by email at *kathleen.mchugh@acf.hhs.gov.* Do not email comments to this address.

SUPPLEMENTARY INFORMATION:

Statutory Authority

This final rule is published under the authority granted to the Secretary of the Department of Health and Human Services by 42 U.S.C. 5101, *et seq.*

In accordance with the Administrative Procedure Act (5 U.S.C. 553), it is the practice of the Secretary to offer interested parties the opportunity to comment on proposed regulations. However, these regulations merely reflect statutory changes and remove unnecessary and obsolete regulatory provisions. Removal of the regulations does not establish or affect substantive policy. Therefore, the Secretary has determined, pursuant to 5 U.S.C. 553(b)(B), that public comment is unnecessary and contrary to the public interest.

Background

There have been major and extensive legislative changes to CAPTA since the CAPTA regulations in 45 CFR part 1340 were issued in 1983 and updated in 1990. The regulations provided guidance to States to implement CAPTA programs that were in effect prior to 1996. These programs changed significantly beginning with the Child Abuse Prevention and Treatment Act Amendments of 1996. This CAPTA reauthorization overhauled the CAPTA state grant program, including the program authorizations for appropriations, making the regulations obsolete. Later, CAPTA reauthorizations also amended the State grant program in section 106 of CAPTA, making the regulations outdated since they do not include all of the CAPTA state grant program requirements contained in the law.

Furthermore, Section 6 of the President's Executive Order 13563 of January 18, 2011 called for retrospective analyses of existing rules ''that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.'' As such, we believe it is unnecessary and outmoded to implement the CAPTA state grant programs through regulation. We believe the program requirements are made clear in the statute and have provided policy interpretations and program instructions to implement the program since 1996 in lieu of regulations. Removing the CAPTA regulations at 45 CFR part 1340 would be in keeping with Executive Order 13563.

In addition, section 109 of CAPTA instructs the Secretary to adopt regulations that are ''necessary or appropriate to ensure that there is effective coordination'' among CAPTA programs. We believe these regulations are no longer necessary or appropriate to ensure coordination because we have provided policy interpretations and program instructions to guide such coordination.

For these reasons, based on our analysis of 45 CFR part 1340, we are removing 45 CFR part 1340 from the Code of Federal Regulations.

Section-by-Section Discussion of the Provisions of This Rule

Subpart A—General Provisions

Section 1340.1 Purpose and Scope

We are removing section 1340.1 because it is outdated and non-essential to the current operations of the CAPTA programs. Paragraphs (a) and (b) clarify the role and activities of the National Center on Child Abuse and Neglect, which no longer exists; paragraph 1340.1(c) is extraneous because it only indicates that the requirements related to child abuse and neglect applicable to title IV–B of the Social Security Act are implemented by regulation at 45 CFR parts 1355 and 1357; and paragraph 1340.1(d) is unnecessary because it simply restates the prohibition on CAPTA funding for the construction of facilities that is provided for in section 108 of CAPTA.

Section 1340.2 Definitions

We are removing the definitions in section 1340.2 because we are removing all of the sections to which the definitions apply. In addition, they are non-essential to the operations of the CAPTA programs for the following reasons. Paragraph (a) defines a ''properly constituted authority'' which is no longer relevant to the state plan requirements; paragraph (b) defines ''Act'' to mean the Child Abuse Prevention and Treatment Act, which is unnecessary; paragraph (c) defines ''Center'' as the National Center on Child Abuse and Neglect, which no longer exists. Paragraph (d) and its subparagraphs define and clarify the terms ''child abuse and neglect'', ''sexual abuse'', ''negligent treatment or maltreatment'', ''threatened harm to a child's health or welfare'' and ''a person responsible for a child's welfare''. These definitions are outdated and superseded by statutory definitions; paragraphs (e) through (h) define ''Commissioner'', ''grants'', ''Secretary'' and ''State'' which are either self-explanatory or defined in statute.

Section 1340.3 Applicability of Department-Wide Regulations

We are removing section 1340.3 because we are removing all of the sections that the Department-wide regulations are applied to by section 1340.3. In addition, these referenced regulations apply to CAPTA programs through the referenced Department-wide regulation itself or are no longer applicable to CAPTA grants.

Sections 1340.3(a) and (b) specify the Department of Health and Human Services regulations that are applicable to all grants and contracts made under this part:

- 45 CFR part 16—Procedures of the Departmental Grant Appeals Board
- 45 CFR part 46—Protection of human subjects
- 45 CFR part 74—Administration of grants
- 45 CFR part 75—Informal grant appeals procedures
- 45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—effectuation of title VI of the Civil Rights Act of 1964
- 45 CFR part 81—Practice and procedure for hearings under part 80
- 45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance
- 48 CFR Chapter 1—Federal Acquisition Regulations
- 48 CFR Chapter 3—Federal Acquisition Regulations—Department of Health and Human Services.

Section 1340.4 Coordination Requirements

We are removing the coordination requirements in section 1340.4 because it is superseded by coordination language in section 101 of CAPTA, enacted in the CAPTA Amendments of 1996.

Subpart B—Grants to States

Sections 1340.10 Purpose of This Subpart, 1340.11 Allocation of Funds Available, 1340.12 Application Process, 1340.13 Approval of Applications, 1340.14 Eligibility Requirements and 1340.15 Services and Treatment for Disabled Infants

We are removing sections 1340.10 through 1340.15 because they are obsolete. Prior to the enactment of the

CAPTA Amendments of 1996, section 107 of CAPTA authorized funding for two State grant programs: (1) To assist States to develop, strengthen and carry out child abuse and neglect prevention and treatment programs; and (2) to assist States in responding to reports of medical neglect (including the withholding of medically indicated treatment from disabled infants with life-threatening conditions), and improving the provision of services to disabled infants with life-threatening conditions and their families. Sections 1340.10 through 1340.14 applied to the former and 1340.15 to the latter and are not applicable to the current CAPTA State grant program in section 106.

The CAPTA Amendments of 1996 and later amendments significantly revised the State grant requirements in law prior to 1996. Now, States must submit a State plan in order to be eligible to receive a grant, including extensive State plan assurances. There is no longer the grant application and approval process specified in the regulations and States now provide assurances in their State plans that certain activities will be carried out using the grant funds to achieve the objectives of the law.

The protections for disabled infants (commonly known as ''Baby Doe'') are now included in the statute in the form of a State plan assurance. Specifically, States are required under section 106(b)(2)(C) of CAPTA to have procedures to respond to reports of withholding medically indicated treatment from disabled infants with life-threatening conditions. In addition ''withholding of medically indicated treatment'' is defined in section 111 of CAPTA. No longer is there a specific State grant program and funding for improving the provision of services to disabled infants with life-threatening conditions and their families.

Subpart C—Discretionary Grants and Contracts

Section 1340.20 Confidentiality

We are deleting section 1340.20 because section 106 of CAPTA addresses requirements for state grantees for confidentiality of records, and confidentiality requirements for other grantees can be addressed in the terms and conditions of the grant.

Appendix to Part 1340—Interpretive Guidelines Regarding CFR 1340.15—Services and Treatment for Disabled Infants

We are deleting the appendix to Part 1340. The appendix was added through a Final Rule (50 FR 14878) in 1985 to implement a grant program made available through the Child Abuse Amendments of 1984 (Pub. L. 98–457). This grant program is no longer in effect as it was at the time the appendix was added (Child Abuse Prevention and Treatment Act Amendments of 1996 (Pub. L. 104–235)).

Paperwork Reduction Act

Under the Paperwork Reduction Act (Pub. L. 104–13), all Departments are required to submit to OMB for review and approval any reporting or recordkeeping requirements inherent in a proposed or final rule. There are no new requirements as a result of this regulation.

Regulatory Flexibility Analysis

The Secretary certifies, under 5 U.S.C. 605(b), and enacted by the Regulatory Flexibility Act (Pub. L. 96–354), that this regulation will not result in a significant impact on a substantial number of small entities.

Regulatory Impact Analysis

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if the regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity.) Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, harmonizing rules, and of promoting flexibility. The regulations we are removing are obsolete and no longer applicable to the current law. By removing these outdated regulations, we are ending potential confusion in regard to the status of the regulations among states, grantees and other affected groups seeking information on the CAPTA program rules. There are no budget implications associated with removing the CAPTA regulations from the Code of Federal Regulations.

Congressional Review

This final rule is not a major rule as defined in 5 U.S.C. Chapter 8.

Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999 requires Federal agencies to determine whether a policy or regulation may negatively affect family well-being. If the agency's determination is affirmative, then the agency must prepare an impact assessment addressing seven criteria specified in the law. The required review of the regulations and policies to determine their effect on family well-being has been completed, and this rule will have a neutral impact on family well-being as defined in the legislation.

Executive Order 13132

Executive Order 13132 prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on State and local governments and is not required by statute, or the rule preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. The regulation has no federalism impact as defined in the Executive Order.

List of Subjects in 45 CFR Part 1340

Child welfare, Grant programs—health, Grant programs—social programs, Individuals with disabilities, Reporting and recordkeeping requirements, Research, Technical assistance, Youth.

Dated: August 18, 2014.

Mark Greenberg,

Acting Assistant Secretary for Children and Families.

Approved: February 27, 2015.

Sylvia M. Burwell,

Secretary.

Editorial note: This document was received for publication by the Office of Federal Register on March 25, 2015.

Subchapter E—[Removed and Reserved]

■ For the reasons discussed above, under the authority at 42 U.S.C. 5101 *et seq.* the Administration for Children and Families amends Title 45, Subtitle B, Chapter XIII, by removing and reserving Subchapter E, consisting of part 1340.

[FR Doc. 2015–07238 Filed 3–27–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 175

[Docket No. PHMSA–2009–0126, Notice No. 15–3]

Hazardous Materials: Spare Fuel Cell Cartridges Containing Flammable Gas Transported by Aircraft in Passenger and Crew Member Checked Baggage

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

ACTION: Notification of a More Definitive Statement.

SUMMARY: PHMSA issued a 2011 final rule in which we did not harmonize with international regulations regarding the carriage of spare fuel cell cartridges in passenger and crew member checked baggage. Lilliputian Systems, Inc. (Lilliputian) contested this final rule, first by filing an administrative appeal, then challenging the final rule in the United States Court of Appeals for the District of Columbia Circuit. On January 31, 2014, the Court remanded the rule and ordered PHMSA to provide further explanation for the prohibition on airline passengers and crew carrying flammable gas fuel cell cartridges in their checked baggage, including its response to Lilliputian's comments. 741 F.3d 1309, 1314 (D.C. Cir. 2014). As a result, we are issuing this document which provides a more thorough explanation and substantial evidence to support PHMSA's decision to prohibit the carriage of spare fuel cell cartridges in passenger and crew member checked baggage.

DATES: March 30, 2015.

FOR FURTHER INFORMATION CONTACT: Michael Stevens, Transportation Specialist (Regulations), Standards and Rulemaking Division, Office of Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590, Telephone: (202) 366–8553 or, via email: *michael.stevens@dot.gov* or Shawn Wolsey, Senior Attorney, Office of the Chief Counsel, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590, (202) 366–4400 or, via email: *shawn.wolsey@dot.gov.*

SUPPLEMENTARY INFORMATION:

Background

In 2009, the International Civil Aviation Organization (ICAO) voted and reissued its Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions), which lifted the previous restriction of spare fuel cell cartridges for all but Division 4.3 chemistries from passenger and crew member checked baggage. In response, on August 24, 2010, the Pipeline and Hazardous Materials Safety Administration (PHMSA) issued a notice of proposed rulemaking (NPRM) to harmonize U.S. Hazardous Materials Regulations (HMR; 49 CFR parts 171–180) with updated international standards. These changes included updates to packaging, labeling, and testing requirements to increase harmony with the international rules and promote the flow of goods (75 FR 52070, HM–215K, 8/24/2010). PHMSA stated its goal was ''. . . to harmonize without diminishing the level of safety currently provided by the HMR and without imposing undue burdens on the regulated public'' and that we ''. . . evaluate[d] each amendment on its own merit.'' [75 FR 52071]

Ultimately, PHMSA did not adopt every provision of every set of the international regulations. In the final rule published January 19, 2011 [76 FR 3308], PHMSA revised the 49 CFR 175.10 passenger exceptions to allow passengers and crew members to place certain spare fuel cell cartridges containing a flammable liquid (Class 3) or corrosive material (Class 8) in checked baggage. PHMSA stated, ''fuel cell cartridges themselves are subject to much more stringent construction, testing, and packaging requirements than for similar articles (*e.g.,* aerosols).'' However, PHMSA limited the scope of spare fuel cell cartridge chemistries allowed in checked baggage by excluding fuel cell cartridges containing Division 2.1 (flammable gas) and Division 4.3 (dangerous when wet) material. In the interest of safety, PHMSA elected to continue the longstanding limitations in the HMR for Division 2.1 (flammable gas) on passenger-carrying aircraft and thus maintained the existing prohibition on the transport of spare fuel cells containing Division 2.1 (flammable gas) in checked baggage. PHMSA and the Federal Aviation Administration (FAA) explained their expressed concern ''due to the questionable integrity of [fuel cells] when packed in a passenger's checked baggage'' [76 FR 3337].

As a result of PHMSA's rulemaking, Lilliputian filed an administrative appeal in accordance with 49 CFR 106.110. It requested PHMSA to revise 49 CFR 175.10(a)(19) to align with the ICAO Technical Instructions and allow spare fuel cell cartridges containing Division 2.1 (flammable gas) to be carried in checked baggage. PHMSA granted the administrative appeal by providing Lilliputian and the public additional opportunity for comment in a May 25, 2012 NPRM [77 FR 31274]. The subsequent final rule issued on January 7, 2013 [78 FR 1101] denied the placement of spare Division 2.1 fuel cell cartridges in checked baggage but continued to allow two spare Division 2.1 fuel cell cartridges in carry-on baggage.

Lilliputian filed a Petition for Review of the Final Order in the United States Court of Appeals for the District of Columbia Circuit on March 8, 2013. In a January 31, 2014, (731 F.3d 1309) decision, the Court remanded the rule and ordered PHMSA to ''provide further explanation for the prohibition on airline passengers and crew carrying flammable-gas fuel cell cartridges in their checked baggage, including its response to Lilliputian's comments.'' [1]

Justification for Denial of the Administrative Appeal

When PHMSA decides whether to allow an item on a passenger-carrying aircraft, the Department only tolerates extraordinarily low levels of risk. For example, when failure of a component in an airplane could interfere with continued flight and safe landing, the risk of failure must be less than one billion to one.[2] This low level of tolerance for risk makes sense because, due to the high volume of air transport, even a very improbable event may eventually occur, and with catastrophic results. Additionally, PHMSA is required by 49 U.S.C. 5108(b) to pursue the ''highest degree of safety in pipeline transportation and hazardous materials transportation.'' [3] Under 49 U.S.C. 5103(b), PHMSA is authorized to issue regulations for the safe and secure transportation of hazardous materials in commerce, including transportation by air.

The risks presented by flammable gas on airplanes are clear. Flammable gases will burn if mixed with an appropriate amount of air, and an ignition source is present, and confined burning of a flammable gas can lead to detonation. As a result, PHMSA remains concerned with the hazards posed by flammable gases (such as the butane contained in some fuel cells) contributing to a fire in the cargo compartment of a passenger-carrying aircraft. This concern is particularly relevant to carriage in checked baggage, where damage to the fuel cell cartridge and the release of a flammable gas may occur if the baggage is mishandled.

PHMSA denied Lilliputian's appeal due to the uncertainty of the safety risks posed when combining (1) the uncertainty of how the baggage handling would affect the durability and stability

[1] 741 F.3d 1314.

[2] *http://www.faa.gov/documentLibrary/media/Advisory_Circular/AC25.1309-1A.pdf.*

[3] PHMSA's Administrator is charged with carrying out all duties and powers vested in the Secretary of Transportation under chapter 51 of Title 49 of the U.S. Code, which governs the transportation of hazardous materials. 49 U.S.C. 108(f)(1).

of these products, (2) the possible oversight of hazmat communication and packaging requirements because the regulations do not apply to passengers, and (3) the limitations of aircraft's fire suppression systems. PHMSA was particularly concerned by the allowance for passengers to transport flammable-gas fuel cells because passengers ''are not trained to recognize potential hazards'' and ''are unlikely to be aware of the safety implications'' of improper packaging or handling. Considering those factors combined with the limitations of the aircraft's suppression system, (fire suppression systems ''do not prevent fires'' and are not ''designed to completely extinguish fires'') the safety risks were too great to authorize this exemption. PHMSA further explained that the authorization of any additional flammable gas on an airplane, in addition to the gases contained in the toiletry and medicinal items already allowed, would need to take into account ''the cumulative risk of the new authorization combined with existing authorizations.'' [78 FR 1104] PHMSA expressed willingness, however, to consider allowing certain fuel cells models on a case-by-case basis. For example, portable oxygen concentrators may be allowed at some point in the future, when experience and testing prove that safe designs exist.

Because of the risks presented by flammable gases, a number of safety requirements apply to shipments of flammable gas on passenger-carrying aircraft. PHMSA believes there is sufficient basis for its decision because, as previously stated, in the area of aviation safety, there is a very low tolerance for risk. In its decision, PHMSA considered the known risks of flammable gases, coupled with the uncertainties relating to the safety of new fuel cell technology, added to the already high volume of air travel and the catastrophic consequences of any failure.

Cumulative Risk

PHMSA's approach to aviation safety is not to permit items merely because they are similar to items already permitted. The authorization of any additional flammable gas on an aircraft, in addition to the toiletry and medicinal items already allowed, needs to take into account the cumulative risk of the new authorization combined with existing authorizations. A limited exception has existed since 1972 for small quantities of such gases in personal medicinal and toiletry items, such as the butane used as a propellant in a small aerosol can or a butane-powered curling iron (49 CFR 175.10(a)(1)(i). However, most Division 2.1 (flammable gas) substances and articles are forbidden from transportation as cargo aboard passenger-carrying aircraft, and thus prohibiting the carriage of spare fuel cell cartridges containing flammable gas in checked baggage is consistent with the agency's longstanding position with regard to flammable gases.

Checked Baggage

The exceptions in 49 CFR 175.10 have not been expanded to permit additional flammable gases in checked baggage. As previously noted, allowing transportation of flammable gas in airline passengers' checked baggage would be inconsistent with the exceptions in 49 CFR 175.10. Airline passengers do not comply with the important packaging, labeling, and hazard communication requirements when they put items in their checked baggage, and they may not even be aware of such requirements. Without hazard communication and other notifications to handlers that the passenger's baggage contains flammable gas, checked baggage could be mishandled, damaging the integrity of an improperly packaged container of flammable gas. Negligent packing and excessive handling increases the potential that a container of flammable gas in checked baggage could rupture, creating conditions for an explosion. 76 FR 3337.

Beginning in 2009, the ICAO began considering whether to change its regulations to allow transport of fuel cells in checked baggage. Prior to that time, fuel cells had been allowed only in carry-on baggage or on one's person, in order to mitigate the risk of the fuel cell cartridge inadvertently coming into contact with an ignition source.[4] Although members of the ICAO Dangerous Goods Panel were generally supportive of permitting most fuel cells containing flammable liquids in checked baggage, ''many were wary of permitting fuel cartridges containing substances of other classes.'' In particular, ''[s]ome felt further consideration was needed with respect to fuel cell cartridges containing flammable gases.'' Some participants suggested that changes not be adopted to allow these new technologies until ''experience based on a longer timeframe could be demonstrated.'' [5] In the end, ICAO included in its Technical Instructions a provision to allow two spare fuel cell cartridges containing flammable gas in checked baggage. It should be noted that the ICAO Dangerous Goods Panel does not operate solely on a consensus basis and that some delegates, including the U.S. Panel Member, were not in agreement with this decision. The U.S. Panel member spoke against the adoption of this provision when the amendment was discussed and agreed to by majority vote during the Dangerous Goods Panel's 22nd meeting (held in Montreal, Canada from October 5–16, 2009).[6]

FAA Technical Report

In Lilliputian's comments posted to the docket of the August 24, 2010 NPRM (PHMSA–2009–0126–2027), they posed five recommendations for conducting a proper risk analysis:

- Any analysis should begin with the risk of ignition or sparking.
- The analysis should examine the risk of catching fire as a result of an external fire.
- The analysis should examine whether a fuel cell fire, once ignited, can be effectively extinguished in a timely manner.
- The analysis should look to any experience involving similar materials.
- The analysis should evaluate whether the volume of the material is relevant in terms of the risk and managing that risk.

We believe that the *Preliminary Investigation of the Fire Hazard Inherent in Micro Fuel Cell Cartridges (Final Report)*[7] prepared by the FAA Technical Center did address these recommendations posed by Lilliputian. The report examined the fire risk presented by fuel cells, including cells powered by flammable solids, liquids, and gas, including a test that exposed single, small fuel cells of various types to a low-intensity flame in a controlled environment. Only a few varieties of fuel cells were tested, because the technology was still developing; however, one of the fuel cells tested was a butane fuel cell manufactured by Lilliputian. The test results showed that, of the fuel types tested, ''[b]utane produced the most vigorous fire.'' The plastic cartridge used by Lilliputian was breached only 45 seconds after exposure

[4] With regard to the allowance of fuel cell cartridges in carry-on baggage or on one's person, the risk is mitigated because the fuel cells are contained in a supervised environment. Thus, a flight attendant would be able to extinguish any fires that might occur in a carry-on bag in the event of a fuel cell cartridge inadvertently coming into contact with an ignition source.

[5] *http://www.icao.int/safety/DangerousGoods/DGP%2022%20Working%20Papers/DGP.22.WP.100.en.pdf at 2.9.4.*

[6] *http://www.icao.int/safety/DangerousGoods/DGP%2022%20Working%20Papers/DGP.22.WP.100.en.pdf.*

[7] See Document PHMSA–2009–0126–2366 in this docket.

to flame and the ''*butane ignition was rapid, almost explosive''*[8] (emphasis added). It produced an approximately 1,000-degree Fahrenheit flame, by far the hottest flame produced by any of the materials in the study. While some of the other fuel cell fires were ''easily extinguished using Halon 1211,'' a fire suppression system commonly used in an aircraft, the butane fire burned so rapidly that the fire suppression system did not activate until after all the butane fuel had been consumed by the fire.

A Halon 1211 system is not designed to detect fires. The pilot must first see that there is an alert from the fire detection system. Once that happens, the pilot will engage the Halon 1211 system, which will attempt to suppress, but not extinguish, the fire. While airplanes are equipped with fire detection systems, such as Halon 1211, there are no systems on board to detect a gas leak. Thus, if a fuel cell cartridge placed in checked baggage is damaged and allows butane gas to leak into the cargo compartment, there is no way for the pilot to be aware of this. The accumulation of the butane gas, if exposed to a spark, would then cause an explosion and would lead to a catastrophic failure of the airplane.

The FAA Technical Center tests were designed to determine the flammability characteristics of fuel cell cartridges. The tests were conducted on single cartridges exposed to a controlled fire. The tests did not take into account the interaction of one or more cartridges and any adjacent combustible material (*i.e.,* clothing, electronic devices, etc.) or the effect of fuel cell cartridges in propagating a fire. We do know from the test results that butane produced the most vigorous fire, the cartridge provided the least amount of protection from an external fire and, once penetrated, the liquid butane burned rapidly and filled the test chamber with fire. The butane fire also registered the highest temperature (1000 degrees Fahrenheit) and heat flux measurements of all tests conducted. The plastic cartridge used by Lilliputian was breached only 45 seconds after exposure to flame, and the butane ignition was rapid, almost explosive. Thus, the test results from the Final Report support our concern that the inherent hazards of compressed flammable gases, as demonstrated by exposure to a fire involving a fuel cell cartridge containing an estimated volume of only 50 cc or less of butane, would pose an unacceptable risk in air transportation.

As PHMSA stated in the preamble to the January 19, 2011 final rule, Federal hazmat law (49 U.S.C. 5101 *et seq.*) and policy encourages the harmonization of domestic and international standards for hazardous materials transportation to the extent practicable, but the law also permits PHMSA to depart from international standards in order to promote public safety. When considering the adoption of international standards under the HMR, PHMSA reviews and evaluates each amendment on its own merit, on the basis of its overall impact on transportation safety, and on the economic implications associated with its adoption. Our goal is to harmonize without diminishing the level of safety and without imposing undue burdens on the regulated public. In this instance, we believe that restricting the carriage of flammable gas fuel cell cartridges to be a necessary variation to the ICAO Technical Instructions that enhances the safety of aircraft passengers without imposing an unreasonable regulatory burden. Under Federal hazmat law, we are tasked with balancing the needs of public safety with economic burdens when considering harmonization with international standards. Consequently, because we elected not to revise the HMR to align with the ICAO Technical Instructions, we believe we did strike a balance by continuing to permit flammable gas fuel cell cartridges in carry-on baggage.

Disparate Treatment of Aerosols and Butane-Powered Articles

The Court of Appeals for the District of Columbia Circuit also was concerned that PHMSA did not provide a reasoned explanation and substantial evidence for the disparate treatment of fuel cell cartridges as opposed to other products, particularly medicinal and toiletry items that contain flammable gases (*i.e.* aerosols).

Aerosols

In order to determine if a hazardous material is permitted in checked baggage, PHMSA must take into account the cumulative risk of any new authorizations combined with any existing authorizations. Under certain conditions, 49 CFR 175.10 permits the carriage of aerosols in checked baggage on a passenger-carrying aircraft. This limited exception has existed since 1972 for aerosol containers in small quantities in personal medicinal and toiletry items. Such items include hair spray, deodorant, and certain medicinal products.

To comply with the ban on chlorofluorocarbons (CFCs) that became effective January 1, 1994,[9] the aerosol industry changed the type of propellant used in their products. Unfortunately, this new type of propellant is flammable and, because of its widespread use, there was concern of a risk-risk tradeoff (ozone layer damage versus cargo compartment safety on passenger-carrying aircraft). PHMSA and FAA were concerned that static electricity inherent in cargo compartments could ignite a leaking flammable aerosol container in passenger baggage.

Based on its concerns, PHMSA reviewed incident reports in the Hazardous Materials Identification System (HMIS) database and specific incidents that occurred during baggage handling provided by the FAA. Accordingly, PHMSA and FAA agreed to work together in certain areas to improve the safe transportation of flammable aerosols by adopting regulatory and non-regulatory solutions. For example, each agency agreed to: (1) Actively participate in the ICAO Dangerous Goods Panel that reviews the items that passengers are permitted to carry in the cabin and in checked baggage; (2) partner with the Consumer Specialty Products Association to enhance the design of aerosol products; and (3) amend the HMR to require or clarify that any release of hazmat in passenger baggage must be reported. Further, in a final rule published on December 20, 2004, PHMSA amended the HMR by requiring that release devices on aerosols be protected by a cap or other suitable means to prevent the inadvertent release of contents when placed in passenger or crew member baggage. [69 FR 76179; (HM–215G)] Because of the prevalence of aerosols in everyday travel, these adopted safety measures were deemed sufficient while not being overly burdensome to the traveling public. However, PHMSA continues to monitor this issue very closely and will respond to any negative trends accordingly.

While PHMSA and FAA adopted safety measures to address the risks associated with permitting aerosols in checked baggage, the amount of butane in a fuel cartridge (200 mL) is approximately twice as much as the amount utilized in a typical 16 ounce aerosol can. Given the amount of electronic devices that passengers typically travel with, the cumulative volume of butane from fuel cell cartridges that passengers could bring aboard an aircraft is a concern. As a result, PHMSA has determined there is too much risk in allowing fuel cell

[8] See Document PHMSA–2009–0126–2366 in this docket.

[9] *http://www.epa.gov/ozone/snap/aerosol/qa.html.*

cartridges in checked baggage in addition to the currently authorized flammable aerosols when stowed in inaccessible cargo compartments on passenger-carrying aircraft.

Butane-Powered Curling Iron Articles

As previously stated, 49 CFR 175.10 prescribes certain conditional exceptions to the HMR for passengers, crewmembers, and air operators for hazardous materials contained in their carry-on (including on one's person) and checked baggage. In paragraph (a)(6), hair curlers (curling irons), containing a hydrocarbon gas such as butane, are excepted from the requirements of the HMR in checked baggage. *Flammable gas refills for such curlers are not permitted in carry-on or checked baggage.* (emphasis added).

In an NPRM published January 23, 2015 (80 FR 3836; [HM–218H]), PHMSA is considering prohibiting butane-powered curling iron articles in checked baggage. We believe the risk posed by flammable gases in an inaccessible compartment on a passenger-carrying aircraft is clear. Flammable gases will burn if mixed with an appropriate amount of air and confined burning of a flammable gas can lead to detonation. As a result, we remain concerned with the flammability hazard posed by butane and other flammable gases and the ability of such gases to propagate or contribute to a fire in the cargo compartment of an aircraft. This concern is particularly relevant to carriage in checked baggage, where damage to the curling iron and the subsequent release of a flammable gas may occur if the baggage is mishandled or the article itself is compromised.

Conclusion

Because of the risks posed by flammable gas, a number of safety requirements apply to cargo shipments of flammable gas on passenger-carrying aircraft. As previously stated, most Division 2.1 (flammable gas) substances and articles are generally forbidden from transportation as cargo aboard passenger-carrying aircraft, and PHMSA's proposal to prohibit the carriage of butane-powered curling irons in checked baggage is consistent with this provision. In the area of aviation safety, where the high volume of travel and the catastrophic consequences of failure lead to a very low tolerance for risk, we firmly believe the known risks of flammable gas are sufficient basis for our decision.

We remain concerned with the flammability hazard posed by butane and other flammable gases and the ability of such gases to propagate or contribute to a fire in an inaccessible cargo compartment of a passenger-carrying aircraft. Moreover, in light of the well-established risks related to flammable gas and the long-standing prohibition of most flammable gas on passenger-carrying aircraft, PHMSA will continue to prohibit fuel cell cartridges that contain a class 2.1 flammable gas from being placed in checked baggage.

Magdy El-Sibaie,

Associate Administrator for Hazardous Materials Safety.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 140501394–5279–02]

RIN 0648–BE20

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Snapper-Grouper Fishery Off the Southern Atlantic States; Amendment 32

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

ACTION: Final rule.

SUMMARY: NMFS issues regulations to implement Amendment 32 to the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP), as prepared by the South Atlantic Fishery Management Council (Council). This rule removes blueline tilefish from the deep-water complex; establishes blueline tilefish commercial and recreational sector annual catch limits (ACLs) and accountability measures (AMs); revises the deep-water complex ACLs and AMs; establishes a blueline tilefish commercial trip limit; and revises the blueline tilefish recreational bag limit. The purpose of this rule is to specify ACLs and AMs for blueline tilefish to end overfishing of the stock and maintain catch levels consistent with achieving optimum yield (OY) for the blueline tilefish resource.

DATES: This rule is effective March 30, 2015.

ADDRESSES: Electronic copies of Amendment 32, which includes an environmental assessment, 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/2014/am32/index.html.*

FOR FURTHER INFORMATION CONTACT: Rick DeVictor, telephone: 727–824–5305, or email: *rick.devictor@noaa.gov.*

SUPPLEMENTARY INFORMATION: The blueline tilefish is a species included in the snapper-grouper fishery of the South Atlantic, and the fishery 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 December 19, 2014, NMFS published a notice of availability for Amendment 32 and requested public comment (79 FR 75780). On January 22, 2015, NMFS published a proposed rule for Amendment 32 and requested public comment (80 FR 3207). The proposed rule and Amendment 32 outline the rationale for the actions contained in this final rule. A summary of the actions implemented by Amendment 32 and this final rule is provided below.

A benchmark assessment for the blueline tilefish stock in the South Atlantic was conducted through the Southeast, Data, Assessment, and Review (SEDAR) process in 2013 (SEDAR 32). The assessment determined that the blueline tilefish stock is undergoing overfishing in the South Atlantic. NMFS published an emergency rule on April 17, 2014 (79 FR 21636), that implemented temporary measures to reduce overfishing of blueline tilefish while Amendment 32 was under development. Those measures were extended through a temporary rule (79 FR 61262, October 10, 2014), and are effective through April 18, 2015. The temporary measures of the emergency action include the following: Removal of blueline tilefish from the deep-water complex, specification of sector ACLs and AMs for blueline tilefish, and revision to the deep-water complex ACL to reflect the removal of blueline tilefish from the complex. Unless otherwise noted, all weights in this rule are expressed in round weight.

Management Measures Contained in This Final Rule

Removal of Blueline Tilefish From the Deep-Water Complex

This final rule removes blueline tilefish from the deep-water complex. In 2012, the Comprehensive ACL Amendment established a deep-water complex that contained the following eight species: Blueline tilefish, yellowedge grouper, silk snapper, misty grouper, queen snapper, sand tilefish, black snapper, and blackfin snapper (77 FR 15916, March 16, 2012).

As a result of blueline tilefish being assessed through SEDAR 32 and the Council's Scientific and Statistical Committee (SSC) providing an assessment-based acceptable biological catch (ABC) recommendation for blueline tilefish, the Council decided to remove blueline tilefish from the deep-water complex and establish individual ACLs and AMs for the blueline tilefish stock. Amendment 29 to the FMP, which was approved by the Secretary of Commerce on February 20, 2015, revised the deep-water complex ABC, and Amendment 32 then revised the deep-water complex commercial and recreational ACLs.

Blueline Tilefish Commercial and Recreational ACLs and AMs

This final rule implements blueline tilefish commercial and recreational ACLs to end overfishing of the stock. The total ACLs (combined commercial and recreational ACLs, equivalent to a total ACL) for blueline tilefish are set at 35,632 lb (16,162 kg) for 2015, 53,457 lb (24,248 kg) for 2016, 71,469 lb (32,418 kg) for 2017, and 87,974 lb (39,904 kg) for 2018, and subsequent fishing years. Based on the sector allocations of 50.07 percent and 49.93 percent for the commercial and recreational sectors, the commercial ACLs are set at 17,841 lb (8,093 kg) for 2015, 26,766 lb (12,141 kg) for 2016, 35,785 lb (16,232 kg) for 2017, and 44,048 lb (19,980 kg) for 2018, and subsequent fishing years. The recreational ACLs are set at 17,791 lb (8,070 kg) for 2015, 26,691 lb (12,107 kg) for 2016, 35,685 lb (16,186 kg) for 2017, and 43,925 lb (19,924 kg) for 2018, and subsequent fishing years.

This final rule implements commercial and recreational in-season AMs for blueline tilefish. If commercial or recreational landings for blueline tilefish reach or are projected to reach the applicable ACL, then the commercial or recreational sector, as applicable, would be closed for the remainder of the fishing year. The recreational sector would not have an in-season closure if the Regional Administrator (RA) determines, using the best scientific information available, that a closure would be unnecessary.

Additionally, if the total ACLs are exceeded in a fishing year, then during the following fishing year the commercial and recreational sectors will not have an increase in their respective ACLs.

This rule also implements post-season ACL overage adjustments (paybacks) for blueline tilefish. For the commercial sector, if commercial landings exceed the commercial ACL, and the total ACL is exceeded, and blueline tilefish are overfished, then during the following fishing year the commercial ACL would be reduced for that following year by the amount of the commercial ACL overage in the prior fishing year. For the recreational sector, if recreational landings for blueline tilefish exceed the applicable recreational ACL, and the total ACL is exceeded, and blueline tilefish are overfished, then the length of the recreational fishing season in the following fishing year would be reduced to ensure recreational landings do not exceed the recreational ACL the following fishing year. Additionally, the recreational ACL would be reduced by the amount of the recreational ACL overage from the prior fishing year. However, the recreational fishing season and recreational ACL would not be reduced if the RA determines, using the best scientific information available that no reduction is necessary.

Additional Blueline Tilefish Management Measures

This final rule implements a commercial trip limit of 100 lb (45 kg), gutted weight; 112 lb (51 kg), round weight, and revises the recreational bag limit for blueline tilefish. The recreational bag limit within the aggregate grouper and tilefish bag limit is set at one per vessel per day for the months of May through August. There is no retention of blueline tilefish by the recreational sector from January through April and from September through December each year.

Deep-Water Complex Commercial and Recreational ACLs and AMs

This final rule revises the ACLs and AMs for the deep-water complex (composed of yellowedge grouper, silk snapper, misty grouper, queen snapper, sand tilefish, black snapper, and blackfin snapper). This rule changes the deep-water complex total ACL (both sectors without blueline tilefish but with the increased catch levels for silk snapper and yellowedge grouper resulting from their increased ABCs in Amendment 29), to 170,278 lb (77,237 kg). Additionally, this rule establishes sector-specific ACLs for the deep-water complex based on the allocations for species in the deep-water complex that were established in the Comprehensive ACL Amendment (77 FR 15916, March 16, 2012). The commercial ACL for the complex is set at 131,634 lb (59,708 kg) and the recreational ACL for the complex is set at 38,644 lb (17,529 kg).

This final rule revises the AMs for the deep-water complex including the commercial post-season AM and the recreational AMs. The commercial post-season AM is revised as follows: If commercial landings exceed the commercial ACL, and the combined commercial and recreational ACL (total ACL) is exceeded, and at least one species in the deep-water complex is overfished, then during the following fishing year the complex commercial ACL would be reduced for that following year by the amount of the complex's commercial ACL overage in the prior fishing year.

The recreational post-season AM is revised as follows: For the recreational sector, if recreational landings for the deep-water complex exceed the applicable recreational ACL, and the combined commercial and recreational ACL is exceeded, and at least one species in the complex is overfished, then the length of the recreational fishing season in the following fishing year would be reduced to ensure recreational landings do not exceed the recreational ACL the following fishing year. Additionally, the recreational ACL would be reduced by the amount of the recreational ACL overage from the prior fishing year. However, the recreational fishing season and recreational ACL would not be reduced if the RA determined, using the best scientific information available, that no reduction is necessary.

Additional Measures Contained in Amendment 32

Amendment 32 also contains actions that are not specified in the regulations. Amendment 32 revises the definitions of management thresholds for South Atlantic blueline tilefish, including maximum sustainable yield (MSY), OY, and ABC, and establishes recreational annual catch targets (ACTs) for blueline tilefish and revises the ACTs for the deep-water complex.

Comments and Responses

A total of 76 comments were received on Amendment 32 and the proposed rule from fishers, a fishing association, and a Federal agency. All of the public comments received were against the proposed actions, with the exception of the comment letter from a Federal agency that had no comment. Specific comments related to the actions contained in Amendment 32 and the proposed rule, and NMFS' respective responses, are summarized and responded to below.

Comment 1: The proposed ACLs are too low. Higher ACLs should be implemented or the ABC and ACLs should be returned to the levels in place before the emergency rule was implemented.

Response: NMFS disagrees that the ACLs being implemented in this final rule are too low. A benchmark assessment for the blueline tilefish stock in the South Atlantic was conducted in 2013 (SEDAR 32). At its October 2013 meeting, the Council's SSC determined the 2013 stock assessment was based on the best scientific information available and considered the assessment to be appropriate for management decisions.

The assessment determined that the blueline tilefish stock is undergoing overfishing in the South Atlantic. As required by the Magnuson-Stevens Act, the Council must therefore implement measures to end overfishing within 2 years of notification of an overfishing status, and NMFS notified the Council of the blueline tilefish stock status on December 6, 2013. If the Council and NMFS allow the ACLs to return to levels in place prior to the emergency rule, overfishing of the blueline tilefish stock would continue.

The ACLs in Amendment 32 are based on the stock assessment and the Council's SSC recommendation for the ABC. In Amendment 32, the Council decided to set the total (stock) ACL at 98 percent of the ABC to account for landings that occur north of the Council's area of jurisdiction. As estimated in SEDAR 32, using data through 2011, approximately 2 percent of the total blueline tilefish harvest was landed north of the North Carolina/Virginia border. NMFS, the Council, and the Mid-Atlantic Fishery Management Council are aware of recent reports of increased landings north of the Council's area of jurisdiction and are considering measures to address the issue.

Comment 2: Beginning in 2015, North Carolina has been requiring catch reports from all for-hire vessels in North Carolina. The Council should wait one more year before taking action in Amendment 32 to allow the incorporation of the information from the North Carolina for-hire catch reports.

Response: The Council and NMFS cannot delay the actions in Amendment 32 to end overfishing of blueline tilefish to include new information being developed in North Carolina beginning in 2015. As required by the Magnuson-Stevens Act, the Council must implement measures to end overfishing within 2 years of notification of an overfishing status, and NMFS notified the Council of the blueline tilefish stock status on December 6, 2013. The next blueline tilefish stock assessment is scheduled to begin in 2016. That assessment will evaluate the available scientific information, including the new for-hire catch reports.

Comment 3: The proposed blueline tilefish recreational bag limit of one per vessel per day from May to August is too low. Implement higher bag limits or retain blueline tilefish in the three fish per person per day grouper and tilefish aggregate bag limit.

Response: NMFS disagrees that the recreational bag limit being established in this final rule is too low. To end overfishing of the blueline tilefish stock in the South Atlantic, the Council and NMFS are implementing blueline tilefish specific ACLs and AMs. One of the recreational AMs is to close the recreational season when the recreational ACL is met or projected to be met. If a higher bag limit were to be implemented, the likelihood of an ACL overage would increase as landings could exceed the recreational ACL before NMFS could close the recreational sector.

A recreational bag limit of one blueline tilefish per vessel per day and an 8-month annual closure was determined to be most likely to end overfishing, reduce recreational harvest, and potentially reduce blueline tilefish discards if blueline tilefish are targeted less during the open season as a result of the reduced bag limit. The Council determined that the shortened summer seasonal opening could provide increased stability to recreational fishers for planning purposes as it could minimize the risk of an in-season closure and the recreational ACL being exceeded, which may require post-season AMs in the following fishing year. In addition, the Council determined that an opening during the summer months could increase safety-at-sea by allowing fishing to occur in the generally calmer summer weather compared to a January 1 season opening during the winter. The recreational bag limit and seasonal closure for the blueline tilefish recreational sector would match what is being proposed by the Council for snowy grouper through Regulatory Amendment 20 to the FMP. The Council determined that similar recreational management measures and fishing seasons would be beneficial to the fish stocks as both species are caught at similar depths and have similar high release mortality rates.

Comment 4: The blueline tilefish commercial trip limit should be 1,000 lb (450 kg) instead of 100 lb (45 kg).

Response: NMFS disagrees that the commercial trip limit should be 1,000 lb (450 kg). The commercial ACL implemented by this rule in 2015 is 17,841 lb (8,093 kg), round weight with a commercial trip limit of 100 lb (45 kg), gutted weight. The commercial AM implemented by this rule is to close the commercial sector when the commercial ACL is met or projected to be met. It is estimated that the combination of the commercial ACL, AM, and trip limit will create a commercial fishing season length of 156 days in 2015. The Council considered a range of trip limit alternatives, including those greater than 100 lb (45 kg). A 1,000-lb (450-kg) trip limit would be likely to greatly reduce the length of the commercial fishing season and increase the likelihood of a derby (race-to-fish) fishery occurring. The Council determined, after reviewing the analysis of the estimated season length, that a trip limit of 100 lb (45 kg), gutted weight, best meets the purpose of ending overfishing while extending the commercial fishing season and minimizing the adverse effects of a derby fishery.

Comment 5: The commercial ACL should be divided 50/50 between the longline and hook-and-line gear components.

Response: The Council did not consider dividing the blueline tilefish commercial ACL into separate ACLs for long-line and hook-and-line gear for the commercial sector in Amendment 32. Therefore, in Amendment 32, the commercial ACL is not further divided by gear type.

Comment 6: Is blueline tilefish overfished and if not, is Amendment 32 legally credible? If blueline tilefish are not overfished, haven't the Council and NMFS already legally ended overfishing as required by law?

Response: The blueline tilefish stock is not overfished but it is undergoing overfishing. Overfishing occurs whenever a stock is subjected to a rate or level of fishing mortality that jeopardizes the capacity of a stock to produce MSY. A stock is overfished when its size is sufficiently small that a change in management practices is required to achieve an appropriate level and rate of rebuilding.

Based on the SEDAR 32 assessment conducted in 2013, NMFS determined that the blueline tilefish stock in the South Atlantic is experiencing overfishing and notified the Council of the stock status on December 6, 2013. At the time, NMFS also notified the Council that the stock was overfished according to the definition of the minimum stock size threshold (MSST). However, since that notification, the Council re-defined the MSST for blueline tilefish and other fish with low natural mortality rates in Regulatory Amendment 21 to the FMP, and blueline tilefish is no longer overfished (79 FR 60379, October 7, 2014). Even though the stock is not overfished, NMFS and the Council must still prepare and implement a plan amendment and regulations to end overfishing of blueline tilefish by December 6, 2015.

Comment 7: The South Atlantic exclusive economic zone (EEZ) should be divided into separate management zones for the Florida Keys and North Carolina. Overfishing is not occurring throughout the entire EEZ and catches should only be limited in the areas where overfishing is occurring.

Response: The Council did not consider regional management zones for blueline tilefish in Amendment 32. The SEDAR 32 stock assessment indicated that blueline tilefish in the South Atlantic is undergoing overfishing throughout the entire South Atlantic and not just for certain areas within the South Atlantic.

The Council has discussed dividing the South Atlantic EEZ into management areas, such as by state or region, several times in reference to various fish species. The Council may revisit these issues and explore such options in the future.

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 and is consistent with Amendment 32, 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.

The Magnuson-Stevens Act provides the statutory basis for this rule. No duplicative, overlapping, or conflicting Federal rules have been identified. In addition, no new reporting, record-keeping, or other compliance requirements are introduced by this final rule.

In compliance with section 604 of the RFA, 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 follows.

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 Regulatory Flexibility Act 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. None of the public comments received specifically concerned the IRFA; however, NMFS received several comments regarding regional differences in recreational for-hire (charter vessel or headboat) fishing businesses indirectly affected by the proposed vessel recreational bag limit and economic impacts of that limit on those businesses.

Several comments did not support the change of the recreational bag limit for blueline tilefish. Presently, an angler can land and possess up to three blueline tilefish per day, and any limit to the number of blueline tilefish landed by a for-hire fishing vessel is only limited by the number of persons on board. This final rule establishes a recreational vessel limit of one blueline tilefish per day from May through August, regardless of how many persons are onboard the vessel, and zero for all other months. Most recreational landings of blueline tilefish have occurred in North Carolina, which indicates for-hire fishing businesses in North Carolina will experience the largest adverse indirect economic impact among the affected for-hire fishing businesses if the recreational bag limit causes demand for for-hire fishing trips to decline.

Up to 681 commercial fishing vessels operate in the snapper-grouper fishery of the South Atlantic and up to 282 of those vessels will be directly affected by this final rule. It is estimated that up to 282 businesses will be directly affected; however, the number of businesses is likely closer to 126, because 126 is the average number of vessels with blueline tilefish landings annually from 2009 through 2013. 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. It is estimated that all of the directly affected businesses have annual revenues less than the size standard. Consequently, up to 282, but more likely closer to 126, small commercial fishing businesses own and operate the directly affected vessels.

Anglers who catch deep-water complex species and blueline tilefish in the EEZ 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. For-hire fishing vessels will be indirectly affected, and as of February 20, 2015, there are up to 1,390 for-hire fishing vessels with a Federal charter vessel/headboat permit for South Atlantic snapper-grouper that will be indirectly affected. The SBA annual receipts threshold for a for-hire fishing business is $7 million (NAICS 487210). It is unknown how many small businesses own and operate the above 1,390 for-hire fishing vessels.

The revised commercial ACL for deep-water complex species is estimated to benefit up to 156, but more likely closer to 126, vessels annually by increasing average annual dockside revenue of each vessel by $1,565, but more likely closer to $1,937 (2012 dollars). If those vessels represent from 126 to 156 small businesses, the average annual benefit would be from $1,937 to $1,565 (2012 dollars), respectively.

The combination of the commercial ACL and in-season AM for blueline tilefish is expected to directly affect 126 vessels and will reduce average annual dockside revenue. The decrease will range from $4,574 to $5,390 (2012 dollars) per vessel. The commercial trip limit for blueline tilefish will reduce the average annual dockside revenue of 21 vessels with a 225-lb (102.1-kg) trip limit snapper-grouper permit by $1,777 each and 105 vessels with an unlimited permit by $5,990 each (2012 dollars). The decrease in average annual dockside revenue caused by the combination of the commercial ACL, AM, and trip limit for blueline tilefish will range from $5,751 to $11,380 (2012 dollars) per vessel and small business.

It is unknown how many of the 126 small businesses referenced above land both deep-water complex species and blueline tilefish. However, if all of the 126 small businesses that land blueline tilefish also account for all of the landings of the deep-water complex species, the annual benefit from increased landings of deep-water complex species and annual cost from decreased landings of blueline tilefish would produce a combined net loss of annual dockside revenue that ranges from $3,814 to $9,443 (2012 dollars) per small business.

No changes were made after publication of the proposed rule to reduce the adverse economic impacts of the rule. However, considered, but not adopted, alternatives included a smaller commercial ACL for the deep-water complex that would have increased the adverse economic impact and a larger commercial ACL and trip limit for blueline tilefish that would have reduced the direct adverse economic impacts of finfish fishing businesses. A larger trip limit, however, would decrease the likelihood that all of the estimated 126 vessels and small businesses, especially the smallest of the small, have blueline tilefish landings during the year. Considered, but not adopted, alternatives would have either increased or decreased the indirect adverse economic impact on for-hire fishing 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.

The AA finds good cause to waive the 30-day delay in effectiveness of the actions in this final rule under 5 U.S.C. 553(d)(3) because it would be contrary to the public interest. Delaying the effectiveness of this rule would be contrary to the public interest because delaying the implementation of the measures contained within this rule is likely to allow the emergency measures to lapse and overfishing of blueline tilefish to continue. The time needed for the Council to develop, approve, and submit Amendment 32 on November 13, 2014, and the required schedules of the Federal rulemaking process did not allow for additional time to be available with respect to this rule's effectiveness and the ending of the emergency measures. Blueline tilefish are currently undergoing overfishing so any delay would undermine the purpose of this rule. If the rule is not implemented immediately, NMFS will likely be required to implement more severe harvest reductions and/or implement AMs that could have greater socio-economic impacts on South Atlantic blueline tilefish fishers. Any delay in the implementation of this final rule would allow the emergency measures to lapse and would allow harvest to continue at a level that is not consistent with National Standard 1 of the Magnuson-Stevens Act. Additionally, delaying the implementation of the measures within this rule for the deep-water complex would be contrary to the public interest as the ACLs for the species within the complex are increasing and thereby this rule increases the potential benefit to fishers with respect to the revised complex ACL.

List of Subjects in 50 CFR Part 622

Blueline tilefish, deep-water complex, Fisheries, Fishing, South Atlantic, Snapper-Grouper.

Dated: March 23, 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 § 622.183, paragraph (b)(7) is added to read as follows:

§ 622.183 Area and seasonal closures.

* * * * *

(b) * * *

(7) *Blueline tilefish recreational sector closure.* The recreational sector for blueline tilefish in or from the South Atlantic EEZ is closed from January 1 through April 30, and September 1 through December 31, each year. During a closure, the bag and possession limit for blueline tilefish in or from the South Atlantic EEZ is zero.

■ 3. In § 622.187, paragraphs (b)(2)(iii) and (iv) are revised and paragraph (b)(2)(v) is added to read as follows:

§ 622.187 Bag and possession limits.

* * * * *

(b) * * *

(2) * * *

(iii) No more than one fish may be a golden tilefish;

(iv) No more than one fish per vessel may be a blueline tilefish; and

(v) No goliath grouper or Nassau grouper may be retained.

* * * * *

■ 4. In § 622.191, paragraph (a)(10) is added to read as follows:

§ 622.191 Commercial trip limits.

* * * * *

(a) * * *

(10) *Blueline tilefish.* Until the applicable ACL specified in § 622.193(z)(1)(iii) is reached or projected to be reached, 100 lb (45 kg), gutted weight; 112 lb (51 kg), round weight. See § 622.193(z)(1)(i) for the limitations regarding blueline tilefish after the commercial ACL is reached.

* * * * *

■ 5. In § 622.193:

■ a. The suspension on paragraph (h) is lifted;

■ b. Paragraph (h) is revised;

■ c. Paragraph (z) is revised; and

■ d. Paragraph (aa) is removed.

The revisions read as follows:

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

* * * * *

(h) *Deep-water complex (including yellowedge grouper, silk snapper, misty grouper, queen snapper, sand tilefish, black snapper, and blackfin snapper)*—(1) *Commercial sector.* (i) If commercial landings for the deep-water complex, as estimated by the SRD, reach or are projected to reach the commercial ACL of 131,634 lb (59,708 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. On and after the effective date of such a notification, all sale or purchase of deep-water complex species 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 commercial landings exceed the ACL, and the combined commercial and recreational ACL (total ACL) specified in paragraph (h)(3) of this section, is exceeded, and at least one of the species in the deep-water 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 commercial ACL for that following year by the amount of the commercial ACL overage in the prior fishing year.

(2) *Recreational sector.* (i) If recreational landings for the deep-water complex, as estimated by the SRD, are projected to reach the recreational ACL of 38,644 lb (17,529 kg), round weight, the AA will file a notification with the Office of the Federal Register to close the recreational sector for the remainder of the fishing year, unless the RA determines that no closure is necessary based on the best scientific information available. On and after the effective date of such a notification, the bag and possession limits are zero.

(ii) If recreational landings for the deep-water complex, exceed the applicable recreational ACL, and the combined commercial and recreational ACL (total ACL) specified in paragraph (h)(3) of this section is exceeded, and at least one of the species in the deep-water 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, to reduce the length of the recreational fishing season in the following fishing year to ensure recreational landings do not exceed the recreational ACL the following fishing year. When NMFS reduces the length of the following recreational fishing season and closes the recreational sector, the following closure provisions apply: The bag and possession limits for the deep-water complex in or from the South Atlantic EEZ are zero. Additionally, the recreational ACL will be reduced by the amount of the recreational ACL overage in the prior fishing year. The fishing season and recreational ACL will not be reduced if the RA determines, using the best scientific information available that no reduction is necessary.

(3) The combined commercial and recreational sector ACL (total ACL) is 170,278 lb (77,237 kg), round weight.

* * * * *

(z) *Blueline tilefish*—(1) *Commercial sector.* (i) If commercial landings for blueline tilefish, as estimated by the SRD, reach or are projected to reach the applicable ACL in paragraph (z)(1)(iii) of this section, 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. On and after the effective date of such a notification, all sale or purchase of blueline tilefish is prohibited and harvest or possession of this 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 commercial landings exceed the ACL, and the combined commercial and recreational ACL (total ACL) specified in paragraph (z)(3) of this section is exceeded, and blueline tilefish are overfished, based on the most recent Status of U.S. Fisheries Report to Congress, the AA will file a notification with the Office of the Federal Register, at or near the beginning of the following fishing year to reduce the commercial ACL for that following year by the amount of the commercial ACL overage in the prior fishing year.

(iii) The applicable commercial ACLs, in round weight, are 17,841 lb (8,093 kg) for 2015, 26,766 lb (12,141 kg) for 2016, 35,785 lb (16,232 kg) for 2017, and 44,048 lb (19,980 kg) for 2018 and subsequent fishing years. The commercial ACL will not increase automatically in a subsequent fishing year if landings exceed or are projected to exceed the total ACL in the prior fishing year, as specified in paragraph (z)(3) of this section.

(2) *Recreational sector.* (i) If recreational landings for blueline tilefish, as estimated by the SRD, are projected to reach the applicable ACL in paragraph (z)(2)(iii) of this section, the AA will file a notification with the Office of the Federal Register to close the recreational sector for the remainder of the fishing year, unless the RA determines that no closure is necessary based on the best scientific information available. On and after the effective date of such a notification, the bag and possession limits are zero.

(ii) If recreational landings for blueline tilefish, exceed the applicable recreational ACL, and the combined commercial and recreational ACL (total ACL) specified in paragraph (z)(3) of this section, is exceeded, and blueline tilefish 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, to reduce the length of the recreational fishing season in the following fishing year to ensure recreational landings do not exceed the recreational ACL the following fishing year. When NMFS reduces the length of the following recreational fishing season and closes the recreational sector, the following closure provisions apply: The bag and possession limits for blueline tilefish in or from the South Atlantic EEZ are zero. Additionally, the recreational ACL will be reduced by the amount of the recreational ACL overage in the prior fishing year. The fishing season and recreational ACL will not be reduced if the RA determines, using the best scientific information available that no reduction is necessary.

(iii) The applicable recreational ACLs, in round weight, are 17,791 lb (8,070 kg) for 2015, 26,691 lb (12,107 kg) for 2016, 35,685 lb (16,186 kg) for 2017, and 43,925 lb (19,924 kg) for 2018 and subsequent fishing years. The recreational ACL will not increase automatically in a subsequent fishing year if landings exceed or are projected to exceed the total ACL in the prior fishing year, as specified in paragraph (z)(3) of this section.

(3) Without regard to overfished status, if the combined commercial and recreational ACL (total ACL), as estimated by the SRD, is exceeded in a fishing year, then during the following fishing year, an automatic increase will not be applied to the commercial and recreational ACLs. The RA will evaluate the landings data, using the best scientific information available, to determine whether or not an increase in the commercial and recreational ACLs will be applied. The applicable combined commercial and recreational sector ACLs (total ACLs), in round weight are 35,632 lb (16,162 kg) for 2015, 53,457 lb (24,248 kg) for 2016, 71,469 lb (32,418 kg) for 2017, and 87,974 lb (39,904 kg) for 2018 and subsequent fishing years.

* * * * *

[FR Doc. 2015–06988 Filed 3–27–15; 8:45 am]

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Proposed Rules

Federal Register
Vol. 80, No. 60
Monday, March 30, 2015

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 932

[Doc. No. AMS–FV–14–0105; FV15–932–1 PR]

Olives Grown in California; Increased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement a recommendation from the California Olive Committee (committee) to increase the assessment rate established for the 2015 and subsequent fiscal years from $15.21 to $26.00 per assessable ton of olives handled. The committee locally administers the marketing order and is comprised of producers and handlers of olives grown in California. Assessments upon olive handlers are used by the committee to fund reasonable and necessary expenses of the program. The fiscal year begins January 1 and ends December 31. The assessment rate would remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Comments must be received by April 29, 2015.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposed rule. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or Internet: *http://www.regulations.gov.* Comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.regulations.gov.* All comments submitted in response to this proposed rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Terry Vawter, Senior Marketing Specialist or Martin Engeler, Regional Manager, California Marketing Field Office, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA; Telephone: (559) 487–5901, Fax: (559) 487–5906, or Email: *Terry.Vawter@ams.usda.gov* or *Martin.Engeler@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.Smutny@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This proposed rule is issued under Marketing Agreement No. 148 and Order No. 932, both as amended (7 CFR part 932), regulating the handling of olives grown in California, 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 proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the marketing order now in effect, California olive handlers are subject to assessments. Funds to administer the order are derived from such assessments. It is intended that the assessment rate increase proposed herein would be applicable to all assessable olives beginning on January 1, 2015, and continue until amended, suspended, or terminated.

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. Such 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 proposed rule would increase the assessment rate established for the committee for the 2015 and subsequent fiscal years from $15.21 to $26.00 per ton of assessable olives.

The California olive marketing order provides authority for the committee, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members of the committee are producers and handlers of California olives. They are familiar with the committee's needs and with the costs for goods and services in their local area and are thus in a position to formulate an appropriate budget and assessment rate.

The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

For the 2014 and subsequent fiscal years, the committee recommended, and USDA approved, an assessment rate that would continue in effect from fiscal year to fiscal year unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the committee or other information available to USDA.

The committee met on December 9, 2014, and unanimously recommended 2015 fiscal year expenditures of $1,374,072, and an assessment rate of $26.00 per ton of assessable olives. Olives are an alternate-bearing crop: a large crop followed by a smaller crop. Olive growers and handlers are accustomed to wide swings in crop yields, which necessarily result in fluctuations in the assessment rate from year to year. In comparison, last year's budgeted expenditures were $1,262,460.

The assessment rate of $26.00 is $10.79 higher than the rate currently in effect.

The committee recommended the higher assessment rate because of a substantial decrease in assessable olive tonnage for the 2014 crop year. The olive tonnage available for the 2014 crop year was less than 40,000 tons, which compares to the 91,000 tons reported for the 2013 crop year, as reported by the California Agricultural Statistics Service (CASS).

The reduced crop is due to olives being an alternate-bearing fruit. The 2014 crop was what is called the ''off'' crop: The smaller of the two bearing-year crops.

In addition to the funds from handler assessments, the committee also plans to use available reserve funds to help meet its 2015 fiscal year expenses.

The major expenditures recommended by the committee for the 2015 fiscal year include $259,231 for research, $450,000 for marketing activities, $122,000 for inspection equipment and electronic reporting development, and $393,500 for administration. The major expenditures for the 2014 fiscal year included $312,560 for research, $565,600 for marketing activities, $37,800 for inspection equipment and electronic reporting development, and $346,500 for administration.

Overall 2015 expenditures include an increase in inspection equipment and electronic reporting development expenses due to the need to purchase, test, install, and link new sizers to the electronic reporting system. Additionally, the research budget contains a contingency of $41,000 for new opportunities that may arise during the fiscal year, and the administrative budget includes a $31,000 contingency for unforeseen issues.

The assessment rate recommended by the committee resulted from consideration of anticipated fiscal year expenses, actual olive tonnage received by handlers during the 2014 crop year, and additional pertinent information. As reported by CASS, actual assessable tonnage for the 2014 crop year is under 40,000 tons or less than half of the 91,000 assessable tons in the 2013 crop year, which is a result of the alternate-bearing characteristics of olives.

Income derived from handler assessments, along with interest income and funds from the committee's authorized reserve would be adequate to cover budgeted expenses. Funds in the reserve would be kept within the maximum permitted by the order of approximately one fiscal year's expenses (§ 932.40).

The proposed assessment rate would continue in effect indefinitely unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the committee or other available information.

Although this assessment rate would be in effect for an indefinite period, the committee would continue to meet prior to or during each fiscal year to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of committee meetings are available from the committee or USDA. Committee meetings are open to the public and interested persons may express their views at these meetings. USDA would evaluate committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking would be undertaken as necessary. The committee's 2015 fiscal year budget and those for subsequent fiscal years would be reviewed and, as appropriate, approved by USDA.

Initial 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 proposed rule on small entities. Accordingly, AMS has prepared this initial 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 the 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 1000 producers of olives in the production area and 2 handlers subject to regulation under the marketing order. The Small Business Administration (13 CFR 121.201) defines small agricultural producers as those having annual receipts of less than $750,000, and small agricultural service firms as those whose annual receipts are less than $7,000,000 (13 CFR 121.210).

Based upon information from the industry and CASS, the average grower price for the 2014 crop year was approximately $1,027 per ton, and total assessable volume was less than 40,000 tons. Based on production, producer prices, and the total number of California olive producers, the average annual producer revenue is less than $750,000. Thus, the majority of olive producers may be classified as small entities. Both of the handlers may be classified as large entities.

This proposed rule would increase the assessment rate established for the committee and collected from handlers for the 2015 and subsequent fiscal years from $15.21 to $26.00 per ton of assessable olives. The committee unanimously recommended 2015 fiscal year expenditures of $1,374,072, and an assessment rate of $26.00 per ton. The higher assessment rate is necessary because assessable olive receipts for the 2014 crop year were reported by CASS to be less than 40,000 tons, compared to 91,000 tons for the 2013 crop year.

Income derived from the $26.00 per ton assessment rate, along with funds from the authorized reserve and interest income, should be adequate to meet this fiscal year's expenses.

The major expenditures recommended by the committee for the 2015 fiscal year include $259,231 for research, $450,000 for marketing activities, $122,000 for inspection equipment development, and $393,500 for administration. Budgeted expenses for these items in 2014 were $312,560 for research, $565,600 for marketing activities, $37,800 for inspection equipment and electronic reporting development, and $346,500 for administration.

The committee deliberated many of the expenses, weighing the relative value of various programs or projects, and decreased their costs for research and marketing, while increasing their costs for inspection equipment and electronic reporting development, as well as their administrative expenses.

Prior to arriving at this budget, the committee considered information from various sources such as the committee's Executive, Marketing, Inspection, and Research Subcommittees. Alternate expenditure levels were discussed by these groups based upon the relative value of various projects to the olive industry and the reduced olive production. The assessment rate of $26.00 per ton of assessable olives was derived by considering anticipated expenses, the volume of assessable olives, and additional pertinent factors.

A review of preliminary information indicates that average grower prices for 2014 crop olives was approximately $1,027 per ton. Therefore, utilizing the proposed assessment rate of $26.00 per ton, the estimated assessment revenue for the 2015 fiscal year as a percentage of total grower revenue would be approximately 2.5 percent.

This action would increase the assessment obligation imposed on

handlers. While assessments impose some additional costs on handlers, the costs are minimal and uniform on all handlers. Some of the additional costs may be passed on to producers. However, these costs would be offset by the benefits derived from the operation of the marketing order. In addition, the committee's meeting was widely publicized throughout the California's olive industry and all interested persons were invited to attend the meeting and participate in committee deliberations on all issues. Like all committee meetings, the December 9, 2014, meeting was a public meeting and all entities, both large and small, were encouraged to express views on this issue. Finally, interested persons are invited to submit comments on this proposed rule including the regulatory and informational impacts of this action on small businesses.

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. 0581–0178. 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 proposed rule would impose no additional reporting or recordkeeping requirements on either small or large California olive 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.

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.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this action.

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.

A 30-day comment period is provided to allow interested persons to respond to this proposed rule. Thirty days is deemed appropriate because: (1) The 2015 fiscal year began on January 1, 2015, and the marketing order requires that the rate of assessment for each fiscal year apply to all assessable olives handled during such fiscal year; (2) the committee needs to have sufficient funds to pay its expenses, which are incurred on a continuous basis; and (3) both regulated handlers were present at the December 9, 2014, meeting, and are aware of this action, which was unanimously recommended by the committee at a public meeting, and is similar to other assessment rate actions issued in past years.

List of Subjects in 7 CFR Part 932

Olives, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 932 is proposed to be amended as follows:

PART 932—OLIVES GROWN IN CALIFORNIA

■ 1. The authority citation for 7 CFR part 932 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 932.230 is revised to read as follows:

§ 932.230 Assessment rate.

On and after January 1, 2015, an assessment rate of $26.00 per ton is established for California olives.

Dated: March 24, 2015.

Rex A. Barnes,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2015–07116 Filed 3–27–15; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 1 and 2

[Docket No. APHIS–2014–0050]

Petition To Define Alternatives to Procedures That May Cause Pain or Distress and To Establish Standards Regarding Consideration of These Alternatives

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of petition.

SUMMARY: We are notifying the public that the Animal and Plant Health Inspection Service has received a petition requesting that we amend the Animal Welfare Act (AWA) regulations to define the term *alternatives,* clarify the existing definition of *painful procedure,* and establish standards governing the consideration of such alternatives at research facilities that are registered under the AWA regulations. We are making this petition available to the public and soliciting comments regarding the petition and any issues raised by the petition that we should take into account as we consider this petition.

DATES: We will consider all comments that we receive on or before May 29, 2015.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0050.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2014–0050, 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-2014-0050* 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: Dr. Carol Clarke, Research Program Manager, USDA, APHIS, Animal Care, 4700 River Road Unit 84, Riverdale, MD 20737–1234; (301) 851–3751.

SUPPLEMENTARY INFORMATION: The Animal Welfare Act (AWA, 7 U.S.C. 2131 *et seq.*) authorizes the Secretary of Agriculture to promulgate standards and other requirements governing research facilities. The Secretary has delegated the responsibility for enforcing the AWA to the Administrator of the Animal and Plant Health Inspection Service (APHIS). Within APHIS, the responsibility for administering the AWA has been delegated to the Deputy Administrator for Animal Care.

Regulations and standards promulgated under the AWA are contained in Title 9 of the Code of Federal Regulations, parts 1, 2, and 3 (referred to collectively below as the AWA regulations). Part 1 contains definitions of terms used within parts 2 and 3. Part 2 contains licensing and registration regulations, regulations specific to research facilities, and regulations governing veterinary care,

animal identification, recordkeeping, access for inspection, confiscation of animals, and handling, among other requirements. Within part 2, subpart C contains the regulations specific to research facilities.

Among other requirements, research facilities, other than Federal research facilities, must register with APHIS and appoint an Institutional Animal Care and Use Committee (IACUC). The IACUC, which must be composed of a chairperson and at least two other members, is required to perform certain functions in order to ensure the facility's compliance with the AWA regulations.

As one of these functions, the IACUC must review proposed activities involving animals that are performed at the facility, as well as significant changes in ongoing activities, in order to determine that the principle investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources used to determine that alternatives were not available.

On October 30, 2013, APHIS received a petition from the Physicians Committee for Responsible Medicine (referred to below as PCRM) requesting that we initiate rulemaking to amend the AWA regulations. Specifically, PCRM asks that we amend part 1 to add a definition of the term *alternatives* in order to delineate what a primary investigator is required to consider in lieu of a procedure that may cause more than momentary or slight pain or distress to the animals. The petition also asks that we amend the existing definition of *painful procedure* in order to codify a long-standing APHIS policy that a procedure should be considered to be painful if it may cause more than momentary or slight pain of distress to the animals, even if this pain is subsequently relieved through anesthesia. Finally, the petition asks that we amend part 2 to specify what must occur as part of a consideration of alternatives.

The petition states that the intent of the AWA is to authorize research facilities to undertake procedures likely to produce pain or distress in animals only if no alternatives exist to these procedures, and that the AWA regulations support this interpretation of the AWA itself. The petition suggests, however, that because of ambiguities in the AWA regulations, research facilities have sometimes construed them to mean that cursory deliberation regarding alternatives suffices to meet this regulatory and statutory requirement to consider alternatives. The petition states that, by amending the AWA regulations in the manner that PCRM suggests, we would remove these ambiguities and facilitate regulatory compliance.

We are making this petition available to the public and soliciting comments to help determine what action, if any, to take in response to this request. The petition and any comments submitted are available for review as indicated under **ADDRESSES** above. We welcome all comments on the issues outlined in the petition. In particular, we invite responses to the following questions:

1. Should APHIS establish regulatory standards for consideration of alternatives to procedures that may cause more than momentary or slight pain or distress to animals?

2. What constitutes an alternative to a procedure that may cause more than momentary or slight pain or distress? If we amend the AWA regulations to define the term *alternative,* what definition should we use?

3. What constitutes a thorough consideration of alternatives? Does this differ depending on the nature of the research conducted? If so, how?

4. Who should make a determination regarding the thoroughness of a primary investigator's consideration of alternatives: The IACUC for a facility, APHIS, or both parties?

5. If the IACUC and APHIS should jointly make a determination, which responsibilities should fall to APHIS and which to the IACUC in terms of evaluating thoroughness?

6. What documentation should the primary investigator provide to demonstrate that he or she has done a thorough consideration of alternatives?

We encourage the submission of scientific data, studies, or research to support your comments and position. We also invite data on the costs and benefits associated with any recommendations. We will consider all comments and recommendations we receive.

Authority: 7 U.S.C. 2131–2159; 7 CFR 2.22, 2.80, and 371.7.

Done in Washington, DC, this 24th day of March 2015.

Jere L. Dick,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015–07221 Filed 3–27–15; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 51, 71, 75, 78, 85, and 86

[Docket No. APHIS–2014–0018]

RIN 0579–AE02

Livestock Marketing Facilities

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: We are reopening the comment period for our proposed rule that would amend the regulations governing approval of facilities that receive livestock moved in interstate commerce, as well as the conditions under which livestock may move to such facilities without official identification or prior issuance of an interstate certificate of veterinary inspection or alternative documentation. This action will allow interested persons additional time to prepare and submit comments.

DATES: The comment period for the proposed rule published on January 2, 2015 (80 FR 6 through 13) is reopened. We will consider all comments that we receive on or before April 15, 2015.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0018.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2014–0018, 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-2014-0018* 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: Mr. Neil Hammerschmidt, Program Manager, Animal Disease Traceability, VS, APHIS, 4700 River Road Unit 200, Riverdale, MD 20737–1236; (301) 851–3539.

SUPPLEMENTARY INFORMATION:

Background

On January 2, 2015, we published in the **Federal Register** (80 FR 6 through 13, Docket No. APHIS–2014–0018) a proposal to amend the regulations in 9 CFR subchapters B and C.

We proposed to amend the regulations in part 51 of subchapter B and several parts of subchapter C to, among other things, replace references to ''approved livestock facilities,'' ''approved stockyards'' and ''specifically approved stockyards'' with the term ''approved livestock marketing facilities.''

We proposed to amend the regulations in § 71.20, which provide the conditions under which the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture may approve a livestock facility to receive livestock that are moved interstate under conditions that are afforded only to such approved facilities. The current regulations in that section require the person legally responsible for the day-to-day operations of the facility to execute an agreement with APHIS regarding the manner in which the facility will operate, if approved. The provisions of the agreement are currently set forth in the regulations.

We proposed to remove the terms of the agreement from the regulations, and place them instead in a document titled ''The Approved Livestock Marketing Facility Agreement,'' which we would maintain on the Internet. We also proposed to update the terms of the agreement and to make other amendments to § 71.20 that would update and clarify the section's content.

We proposed to revise § 86.4 in order to clarify the conditions under which cattle and bison may be moved interstate to an approved livestock marketing facility without official identification. We also proposed to revise § 86.5 in order to clarify the conditions under which cattle or bison may be moved interstate to an approved livestock facility without an accompanying interstate certificate of veterinary inspection or owner-shipper statement.

Comments on the proposed rule were required to be received on or before March 3, 2015. We are reopening the comment period on Docket No. APHIS–2014–0018. The comment period will now close on April 15, 2015. We will also accept all comments received between March 4, 2015 (the day after the close of the original comment period) and the date of this notice. This action will allow interested persons additional time to prepare and submit comments.

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 24th day of March 2015.

Jere L. Dick,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015–07217 Filed 3–27–15; 8:45 am]

BILLING CODE 3410–34–P

FEDERAL ELECTION COMMISSION

11 CFR Part 111

[Notice 2015–05]

Rulemaking Petition: Administrative Fines Program and Commission Forms

AGENCY: Federal Election Commission.

ACTION: Rulemaking Petition: Notice of availability.

SUMMARY: On January 23, 2015, the Federal Election Commission received a Petition for Rulemaking asking the Commission to expand its Administrative Fines Program and to revise and update several Commission forms and their instructions. The Commission seeks comments on this petition.

DATES: Comments must be submitted on or before May 29, 2015.

ADDRESSES: All comments must be in writing. Commenters are encouraged to submit comments electronically via the Commission's Web site at *http://www.fec.gov/fosers,* reference REG 2015–01, or by email to *FinesAndForms@fec.gov.* Alternatively, commenters may submit comments in paper form, addressed to the Federal Election Commission, Attn.: Robert M. Knop, Assistant General Counsel, 999 E Street NW., Washington, DC 20463.

Each commenter must provide, at a minimum, his or her first name, last name, city, state, and zip code. All properly submitted comments, including attachments, will become part of the public record, and the Commission will make comments available for public viewing on the Commission's Web site and in the Commission's Public Records room. Accordingly, commenters should not provide in their comments any information that they do not wish to make public, such as a home street address, personal email address, date of birth, phone number, social security number, or driver's license number, or any information that is restricted from disclosure, such as trade secrets or commercial or financial information that is privileged or confidential.

FOR FURTHER INFORMATION CONTACT: Mr. Robert M. Knop, Assistant General Counsel, Mr. Neven F. Stipanovic, Attorney, or Ms. Holly Ratliff, Office of General Counsel, 999 E Street NW., Washington, DC 20463, (202) 694–1650 or (800) 424–9530.

SUPPLEMENTARY INFORMATION: On January 23, 2015, the Federal Election Commission received a Petition for Rulemaking from seven attorneys [1] (collectively ''petitioners'') regarding the Commission's Administrative Fines Program (''AFP'') and several of the Commission's forms and their accompanying instructions. Under the AFP, the Commission assesses civil monetary penalties for late filing and failure to file certain reports as required by 52 U.S.C. 30104(a) (formerly 2 U.S.C. 434(a)) (requiring political committee treasurers to report receipts and disbursements within certain time periods). 11 CFR 111.30; *see also* 52 U.S.C. 30109(a)(4)(C) (formerly 2 U.S.C. 437g(a)(4)(C)). If the Commission determines that such a violation has occurred, it may assess a civil monetary penalty according to the AFP penalty schedules at 11 CFR 111.43–.44.

In December 2013, Congress authorized the Commission to expand the scope of the AFP to encompass reporting violations for reports filed under 52 U.S.C. 30104(c) (formerly 2 U.S.C. 434(c)) (certain independent expenditure reports), 52 U.S.C. 30104(e) (formerly 2 U.S.C. 434(e)) (certain federal election activity reports), 52 U.S.C. 30104(f) (formerly 2 U.S.C. 434(f)) (electioneering communications reports), 52 U.S.C. 30104(g) (formerly 2 U.S.C. 434(g)) (24- and 48-hour independent expenditure reports), 52 U.S.C. 30104(i) (formerly 2 U.S.C. 434(i)) (bundled contribution reports), and 52 U.S.C. 30105 (formerly 2 U.S.C. 437) (certain convention reports). *See* Public Law 113–72, 127 Stat. 1210 (2013). The petitioners ask the Commission to conduct a rulemaking to expand the scope of the AFP to these additional categories of reporting violations, using an approach that considers the criteria in the penalty schedule found at 11 CFR 111.43 (election sensitivity, level of activity, number of days late, and number of previous violations) and similar factors but eschews a strict formulaic penalty.

The petitioners also ask the Commission to revise several of its

[1] Messrs. Robert F. Bauer, Allen Dickerson, Benjamin L. Ginsberg, Donald F. McGahn II, Laurence E. Gold, Robert D. Lenhard, and Bradley A. Smith.

forms and their instructions. The proposals are divided into five categories, wherein the petitioners ask the Commission to: (1) Eliminate the need for ''sophisticated accounting techniques'' by ''add[ing] a single, streamlined page to Form 3X for reporting all in-kind contributions'' and ''clarify[ing] that committees need only engage in best efforts to reasonably ascertain the value of expenditures subject to 24- and 48-hour reports''; (2) revise the forms to ''reflect the existence of independent-expenditure only committees''; (3) revise the forms to ''reflect the existence of *Carey* funds''; (4) revise the forms to ''recognize that corporations and labor organizations may make contributions to IE PACs''; and (5) revise the forms to ''confine Form 3X to nonconnected committees and separate segregated funds, create a separate reporting form for political party committees, and thoroughly redesign Form 3X.''

The Commission seeks comments on the petition. The public may inspect the Petition for Rulemaking on the Commission's Web site at *http://www.fec.gov/fosers,* or in the Commission's Public Records Office, 999 E Street NW., Washington, DC 20463, Monday through Friday, from 9 a.m. to 5 p.m. Interested persons may also obtain a copy of the petition by dialing the Commission's Faxline service at (202) 501–3413 and following its instructions. Request document #277.

The Commission will not consider the petition's merits until after the comment period closes. If the Commission decides that the petition has merit, it may begin a rulemaking proceeding. The Commission will announce any action that it takes in the **Federal Register**.

On behalf of the Commission.
Dated: March 24, 2015.

Ann M. Ravel,

Chair, Federal Election Commission.

[FR Doc. 2015–07176 Filed 3–27–15; 8:45 am]

BILLING CODE 6715–01–P

FEDERAL ELECTION COMMISSION

11 CFR Part 115

[Notice 2015–06]

Rulemaking Petition: Federal Contractors

AGENCY: Federal Election Commission.

ACTION: Rulemaking Petition: Notice of availability.

SUMMARY: On November 18, 2014, the Federal Election Commission received a Petition for Rulemaking from Public Citizen. The petitioner asks the Commission to amend its regulations regarding federal contractors to include certain factors for determining whether entities of the same corporate family are distinct business entities for purposes of the prohibition on contributions by federal contractors. The Commission seeks comments on this petition.

DATES: Comments must be submitted on or before May 29, 2015.

ADDRESSES: All comments must be in writing. Commenters are encouraged to submit comments electronically via the Commission's Web site at *http://www.fec.gov/fosers,* reference REG 2014–09, or by email to *ContractorPetition@fec.gov*. Alternatively, commenters may submit comments in paper form, addressed to the Federal Election Commission, Attn.: Amy L. Rothstein, Assistant General Counsel, 999 E Street NW., Washington, DC 20463.

Each commenter must provide, at a minimum, his or her first name, last name, city, state, and zip code. All properly submitted comments, including attachments, will become part of the public record, and the Commission will make comments available for public viewing on the Commission's Web site and in the Commission's Public Records room. Accordingly, commenters should not provide in their comments any information that they do not wish to make public, such as a home street address, personal email address, date of birth, phone number, social security number, or driver's license number, or any information that is restricted from disclosure, such as trade secrets or commercial or financial information that is privileged or confidential.

FOR FURTHER INFORMATION CONTACT: Mrs. Amy L. Rothstein, Assistant General Counsel, or Mr. Neven F. Stipanovic, Attorney, 999 E Street NW., Washington, DC 20463, (202) 694–1650 or (800) 424–9530.

SUPPLEMENTARY INFORMATION: On November 18, 2014, the Commission received a Petition for Rulemaking from Public Citizen regarding part 115 of the Commission's regulations. Part 115 prohibits federal contractors from making contributions or expenditures to any political party, political committee, or federal candidate, or to any person for any political purpose or use. 11 CFR 115.2(a); *see also* 52 U.S.C. 30119(a)(1) (formerly 2 U.S.C. 441c(a)(1)). Part 115 further prohibits any person from knowingly soliciting a contribution from any federal contractor. 11 CFR 115.2(c); *see also* 52 U.S.C. 30119(a)(2) (formerly 2 U.S.C. 441c(a)(2)). The petitioner asks the Commission to amend 11 CFR part 115 to include certain factors for determining whether entities of the same corporate family are distinct business entities for purposes of these prohibitions. The Commission seeks comments on the petition.

The public may inspect the Petition for Rulemaking on the Commission's Web site at *http://www.fec.gov/fosers,* or in the Commission's Public Records Office, 999 E Street, NW., Washington, DC 20463, Monday through Friday, from 9 a.m. to 5 p.m. Interested persons may also obtain a copy of the petition by dialing the Commission's Faxline service at (202) 501–3413 and following its instructions. Request document #276.

The Commission will not consider the petition's merits until after the comment period closes. If the Commission decides that the petition has merit, it may begin a rulemaking proceeding. The Commission will announce any action that it takes in the **Federal Register**.

On behalf of the Commission,
Dated: March 24, 2015.

Ann M. Ravel,

Chair, Federal Election Commission.

[FR Doc. 2015–07177 Filed 3–27–15; 8:45 am]

BILLING CODE 6715–01–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 701

RIN 3133–AE39

Federal Credit Union Ownership of Fixed Assets

AGENCY: National Credit Union Administration (NCUA).

ACTION: Proposed rule.

SUMMARY: The NCUA Board (Board) is issuing for public comment this proposed rule (2015 proposal) to amend its regulation governing federal credit union (FCU) ownership of fixed assets. To provide regulatory relief to FCUs, the 2015 proposal eliminates a provision in the current fixed assets rule that established a five percent aggregate limit on investments in fixed assets for FCUs with $1,000,000 or more in assets. It also eliminates the provisions in the current fixed assets rule relating to waivers from the aggregate limit. Further, instead of applying the prescriptive aggregate limit provided by regulation in the current fixed assets rule, the Board proposes to oversee FCU ownership of fixed assets through the

supervisory process and guidance. The 2015 proposal also makes conforming amendments to the scope and definitions sections of the current fixed assets rule to reflect this proposed approach, and it amends the title of § 701.36 to more accurately reflect this amended scope and applicability.

In addition, the 2015 proposal simplifies the fixed assets rule's partial occupancy requirements for FCU premises acquired for future expansion by establishing a single six-year time period for partial occupancy of such premises and by removing the 30-month requirement for partial occupancy waiver requests. The Board notes that, in July 2014, it issued a proposal regarding the fixed assets rule that addressed, among other things, the partial occupancy provisions of the fixed assets rule (July 2014 proposal), but NCUA did not finalize that proposal. For reasons discussed below, the 2015 proposal incorporates similar partial occupancy proposed amendments from the July 2014 proposal, with one modification to the time period for partial occupancy.

DATES: Comments must be received on or before April 29, 2015.

ADDRESSES: You may submit comments by any of the following methods (Please send comments by one method only):

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *NCUA Web site: http://www.ncua.gov/RegulationsOpinionsLaws/proposed_regs/proposed_regs.html.* Follow the instructions for submitting comments.
- *Email:* Address to *regcomments@ncua.gov.* Include ''[Your name] Comments on Notice of Proposed Rulemaking for Part 701, FCU Ownership of Fixed Assets'' in the email subject line.
- *Fax:* (703) 518–6319. Use the subject line described above for email.
- *Mail:* Address to Gerard Poliquin, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.
- *Hand Delivery/Courier:* Same as mail address.

Public Inspection: You may view all public comments on NCUA's Web site at *http://www.ncua.gov/Legal/Regs/Pages/PropRegs.aspx* as submitted, except for those we cannot post for technical reasons. NCUA will not edit or remove any identifying or contact information from the public comments submitted. You may inspect paper copies of comments in NCUA's law library at 1775 Duke Street, Alexandria, Virginia 22314, by appointment weekdays between 9 a.m. and 3 p.m. To make an appointment, call (703) 518–6546 or send an email to *OGCMail@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: Pamela Yu, Senior Staff Attorney, Office of General Counsel, at the above address or telephone (703) 518–6540, or Jacob McCall, Program Officer, Office of Examination and Insurance, at the above address or telephone (703) 518–6360.

SUPPLEMENTARY INFORMATION:

I. Background
A. 2013 Rule
B. July 2014 Proposal
C. Public Comments on the July 2014 Proposal
II. Summary of the 2015 Proposal
III. Request for Public Comment
IV. Regulatory Procedures

I. Background

The Federal Credit Union Act (FCU Act) authorizes an FCU to purchase, hold, and dispose of property necessary or incidental to its operations.[1] NCUA's fixed assets rule interprets and implements this provision of the FCU Act.[2] NCUA's current fixed assets rule: (1) Limits FCU investments in fixed assets; (2) establishes occupancy, planning, and disposal requirements for acquired and abandoned premises; and (3) prohibits certain transactions.[3] Under the current rule, fixed assets are defined as premises, furniture, fixtures, and equipment, including any office, branch office, suboffice, service center, parking lot, facility, real estate where a credit union transacts or will transact business, office furnishings, office machines, computer hardware and software, automated terminals, and heating and cooling equipment.[4]

A. 2013 Rule

The Board has a policy of continually reviewing NCUA's regulations to update, clarify and simplify existing regulations and eliminate redundant and unnecessary provisions. To carry out this policy, NCUA identifies one-third of its existing regulations for review each year and provides notice of this review so the public may comment. In 2012, NCUA reviewed its fixed assets rule as part of this process. As a result of that review, in March 2013, the Board issued proposed amendments to the fixed assets rule to make it easier for FCUs to understand it.[5] The proposed amendments did not make any substantive changes to the regulatory requirements. Rather, they only clarified the rule and improved its overall organization, structure, and readability.

In response to the Board's request for public comment on the March 2013 proposal, several commenters offered suggestions for substantive changes to the fixed assets rule, such as increasing or eliminating the aggregate limit on fixed assets, changing the current waiver process, and extending the time frames for occupying premises acquired for future expansion. These comments, however, were beyond the scope of the March 2013 proposal, which only reorganized and clarified the rule. Accordingly, in September 2013, the Board adopted the March 2013 proposal as final without change except for one minor modification.[6] In finalizing that rule, however, the Board indicated it would take the commenters' substantive suggestions into consideration if it were to make subsequent amendments to NCUA's fixed assets rule.

B. July 2014 Proposal

In July 2014, the Board issued a proposed rule to provide regulatory relief to FCUs and to allow FCUs greater autonomy in managing their fixed assets.[7] These amendments reflected some of the public comments received on the March 2013 proposal. Specifically, in the July 2014 proposal, the Board proposed to allow an FCU to exceed the five percent aggregate limit,[8] without the need for a waiver, provided that the FCU implemented a fixed asset management (FAM) program that demonstrated appropriate pre-acquisition analysis to ensure the FCU could afford any impact on earnings and net worth levels resulting from the purchase of fixed assets. Under the July 2014 proposal, an FCU's FAM program would have been subject to supervisory scrutiny and would have had to provide for close ongoing oversight of fixed assets levels and their effect on the FCU's financial performance. It also would have had to include a written policy that set an FCU board-established limit on the aggregate amount of the FCU's fixed assets. In the July 2014 proposal, the Board also proposed to simplify the partial occupancy requirement for premises acquired for future expansion by establishing a single five-year time period for partial occupancy of any premises acquired for future expansion, including improved

[1] 12 U.S.C. 1757(4).
[2] 12 CFR 701.36.
[3] Id.
[4] 12 CFR 701.36(c).
[5] 78 FR 17136 (Mar. 20, 2013).
[6] 78 FR 57250 (Sept. 18, 2013).
[7] 79 FR 46727 (Aug. 11, 2014).
[8] The five percent aggregate limit on fixed assets is measured in comparison to the FCU's shares and retained earnings.

and unimproved property, and by removing the current fixed assets rule's 30-month time limit for submitting a partial occupancy waiver request.

C. Public Comments on the July 2014 Proposal

The public comment period for the July 2014 proposal ended on October 10, 2014. NCUA received thirty-six comments on the proposal: Two from credit union trade associations; one from a bank trade association; sixteen from state credit union leagues; thirteen from FCUs; three from federally insured, state-chartered credit unions; and one from an individual. While commenters generally supported the Board's efforts to provide regulatory relief from the requirements concerning FCU fixed assets, most commenters advocated more relief or suggested alternative approaches to achieving that objective.

One commenter fully supported all aspects of the July 2014 proposal. Two commenters opposed it, and another commenter stated that it represented only a marginal improvement over the current rule.

1. Removal of the Waiver Requirement To Exceed the Five Percent Aggregate Limit

Under the current rule, if an FCU has $1,000,000 or more in assets, the aggregate of all its investments in fixed assets must not exceed five percent of its shares and retained earnings, unless it obtains a waiver from NCUA.[9] In the July 2014 proposal, the Board proposed to amend this requirement to allow an FCU to exceed the five percent aggregate limit, without a waiver, provided the FCU implemented a FAM program to manage and monitor the FCU's fixed assets.

Fifteen commenters supported removing the waiver requirement and also supported the requirement to adopt a FAM program for those FCUs that exceed the five percent limit. Five commenters, however, supported removing the waiver requirement but disagreed with the FAM program requirement. One commenter did not support the removal of the waiver requirement.

a. Five Percent Aggregate Limit

In the July 2014 proposal, the Board did not propose to change the current rule's five percent aggregate limit on an FCU's investment in fixed assets, but many commenters nonetheless advocated its repeal. At least ten commenters suggested that the July 2014 proposal did not provide sufficient regulatory relief and that the five percent aggregate limit should be eliminated. These commenters noted that the aggregate limit is not statutorily mandated by the FCU Act and, thus, FCUs should be allowed to independently manage their own fixed assets by setting their own credit union board-approved limits. Four commenters argued further that FCUs should be permitted to set their own fixed assets limits without the additional requirement of adopting a burdensome FAM program.

One commenter, however, urged NCUA not to eliminate the aggregate limit because allowing unlimited amounts of investments in fixed assets could pose a significant safety and soundness risk. The same commenter observed that the material loss reviews of several failed FCUs noted the contributory role that excessive fixed assets played in those credit union failures.

Other commenters were not opposed to an aggregate limit, but argued it should be increased. For example, one commenter advocated a fifteen percent aggregate limit. Another suggested that the aggregate limit should be raised to at least twenty percent.

b. Exclusions From the Fixed Assets Ratio

A number of commenters recommended that certain investments should be excluded from the current rule's fixed assets ratio calculation. Two commenters stated generally that the fixed assets calculation should reflect the greater emphasis placed on technology in the current marketplace and better account for the need to replace obsolete technology and equipment. At least four commenters stated that investments in information technology, including computer hardware and software, should be excluded from the calculation. One commenter indicated that fixed assets should be comprised of land and buildings only. Another commenter stated generally that there should be some type of safe harbor or exclusion to allow for the purchase of necessary equipment.

2. Fixed Assets Management Program

Fifteen commenters supported the proposed requirement for an FCU to adopt a FAM program before choosing to exceed the five percent aggregate limit. However, most commenters that generally supported this aspect of the proposal also expressed concerns about certain aspects of the requirement.

Approximately one quarter of the commenters opposed the FAM program requirement altogether. Of those, several commenters argued that it is unnecessary or overly burdensome, and it would impose additional burdens that FCUs are not already subject to under the current rule. For example, four commenters noted that the requirement for annual FCU board review is an additional step that is not present under the current waiver process. One commenter argued that the FAM program requirement would create unnecessary complications to the acquisition of fixed assets over the five percent limit, and the requirement could serve as a deterrent to the acquisition of fixed assets. One commenter argued that the proposal simply shuffles regulatory burden, rather than providing meaningful regulatory relief. Another commenter also argued that the level of analysis that must be included in an FCU's FAM program is beyond what is required under the current waiver process and, thus, the proposal would not reduce regulatory burden. Three commenters proffered a similar argument that the additional requirements imposed after assets are acquired would increase FCUs' compliance responsibilities and costs, negating any flexibility gained under the proposal.

a. Minor Acquisitions

Four commenters requested changes to proposed § 701.36(c)(2), which would require an FCU to seek FCU board approval to make investments in fixed assets exceeding the aggregate limit ''except for the minor acquisitions of equipment in the normal course of business.'' A number of commenters suggested this language should be expanded to include minor acquisitions of furniture and fixtures, in addition to equipment. One commenter suggested ''minor acquisitions'' should specifically include purchases of desktop technologies, such as computer monitors, printers, faxes, scanners, copiers, and telephones, upgrades or renewals to existing desktop software, and ATMs. Another commenter suggested that ''minor acquisitions'' should be defined as anything under .005 percent of shares and retained earnings.

b. Future Marketability

At least seven commenters expressed concern with the ''future marketability'' element of the FAM program. Specifically, proposed § 701.36(2)(iii) provided that FCU board oversight of an investment in real property that would cause the FCU to exceed the five percent aggregate limit must reflect the board's consideration of the ''future

[9] 12 CFR 701.36(c).

marketability'' of the premises. Commenters noted that this requirement could, in some circumstances, be contrary to the best interest of members, particularly low-income members and members in rural or underserved areas. They argued that the decision to purchase a branch or office location should be based on member service needs, not future marketability. At least four commenters requested that the future marketability provision be eliminated because strategic considerations beyond marketability factor into a decision to acquire fixed assets.

c. Internal Controls

Proposed § 701.36(c)(3) would have required an FCU's FAM program to establish ongoing internal controls to monitor and measure the FCU's investments in fixed assets. Two commenters disagreed with the proposed internal controls requirement, noting that the current fixed assets rule does not have a specific internal controls requirement. These commenters argued that internal controls to monitor fixed assets investments should not be prescribed by specific regulatory requirements, but rather such internal controls should be determined by credit union management and subject to examiner review during the routine examination process.

d. Appeals

Eight commenters suggested that any final rule should include an appeals process to allow, for example, an FCU to appeal if an examiner contests an FCU's fixed asset investment or disapproves an FCU's FAM program.

e. Conclusion Regarding Aggregate Limit and FAM Program

After careful consideration of the public comments relating to the fixed assets aggregate limit, the Board has determined that additional regulatory relief beyond what was provided in the July 2014 proposal is warranted. Therefore, the Board is not adopting the July 2014 proposed amendments relating to the five percent aggregate limit on fixed assets, including any FAM program requirements. In particular, upon further review, the Board has concluded that oversight of the purchase of FCU investments in fixed assets can be effectively achieved through supervisory guidance and the examination process, rather than through prescriptive regulatory limitations. Accordingly, the Board is issuing this 2015 proposal to remove altogether the five percent aggregate limit on fixed assets, as discussed in further detail below.

D. Partial Occupancy

The July 2014 proposal also would have simplified the partial occupancy requirement for premises acquired for future expansion. Virtually all commenters that provided feedback on the proposed amendments to the partial occupancy requirement supported the overall concept of streamlining or improving this aspect of the fixed assets rule. However, as discussed more fully below, most commenters requested additional relief beyond that proposed.

1. Time Period for Partial Occupancy

Under the current rule, if an FCU acquires premises for future expansion and does not fully occupy them within one year, it must have an FCU board resolution in place by the end of that year with definitive plans for full occupation. In addition, the rule requires an FCU to partially occupy the premises within a reasonable period, but no later than three years after the date of acquisition, or six years if the premises are unimproved land or unimproved real property. In the July 2014 proposal, the Board proposed to simplify this aspect of the fixed assets rule by establishing a single time period of five years from the date of acquisition for partial occupancy of any premises acquired for future expansion, regardless of whether the premises are improved or unimproved.

Three commenters agreed with the proposal to establish a single, uniform five-year time period for partial occupancy of any premises acquired for future expansion. Of those, one commenter stated that an increase of two years for partial occupancy of improved property is a beneficial trade-off for the one year reduction in the timeframe for partial occupancy of unimproved property. The same commenter noted that a single timeframe is easier for compliance purposes.

Two commenters supported a uniform time period, but suggested that five years is insufficient. They recommended that, at a minimum, it should be a uniform six years, as previously provided for unimproved property. Seven commenters suggested that the time period for partial occupancy should be extended to ten years.

Eight commenters agreed with extending the partial occupancy requirement for improved premises from three to five years, but disagreed with reducing the partial occupancy requirement for unimproved property from six to five years. Of those, two commenters posited that reducing the timeframe would increase an FCU's regulatory burden.

One commenter suggested that the current partial occupancy requirements should be retained, but the rule should require an FCU (or a combination of an FCU, credit union service organization, and/or credit union vendor) to occupy at least 51 percent of the premises to meet the partial occupancy requirement. This commenter argued that relaxing the partial occupancy requirement would encourage FCUs to maximize non-mission related income by leasing out their property. The same commenter further stated that because FCUs are not subject to unrelated business income taxes, they have an incentive to maximize leasing income by delaying occupancy, and this would be an abuse of the credit union tax exempt status. Another commenter also supported retaining separate timeframes for improved and unimproved property, but suggested that both time periods should be lengthened to five years and eight years, respectively.

Approximately thirteen commenters suggested that regulatory timeframes for occupancy should be eliminated entirely. These commenters generally argued that an FCU should have the ability to make its own determination, in its FAM program or by board policy, about how much time it needs to reach full or partial occupancy of its property.

The Board has carefully weighed these comments, but disagrees with commenters who suggested that regulatory timeframes for occupancy should be eliminated.

Unlike the five percent aggregate limit, which is a safety and soundness safeguard but is not statutorily required, the occupancy requirements in the fixed assets rule have statutory underpinnings. As discussed in the preamble to the July 2014 proposal, an FCU may not hold (or lease to unrelated third parties) real property indefinitely without fully occupying the premises. Section 107(4) of the FCU Act authorizes an FCU to purchase, hold, and dispose of property *necessary or incidental to its operations.*[10] NCUA has long held that this provision means an FCU may only invest in property it intends to use to transact credit union business or in property that supports its internal operations or member services.[11] There is no authority in the

[10] 12 U.S.C. 1757(4) (emphasis added).

[11] *See* 43 FR 58176, 58178 (Dec. 13, 1978) (''Part 107(4) of the Federal Credit Union Act provides that a credit union may purchase, hold, and dispose of property necessary or incidental to its operations.

FCU Act for an FCU to invest in real estate for speculative purposes or to otherwise engage in real estate activities that do not support its purpose of providing financial services to its members. While there is no required timeframe in the fixed assets rule within which an FCU must achieve full occupation, the rule requires an FCU to partially occupy the premises within a time period set by the rule and sufficient to show, among other things, that the FCU will fully occupy the premises within a reasonable time.[12]

The Board emphasizes that FCUs already have significant leeway and flexibility in managing real property acquired for future use, given that there is no required time period for full occupation. Moreover, the proposed elimination of the 30-month requirement for partial occupancy waiver requests, which is discussed below, would allow FCUs additional leeway to apply for a waiver later if it deemed appropriate.

The Board continues to believe that, as discussed in the preamble to the July 2014 proposal, a single time period for partial occupancy would simplify and improve the rule.[13] However, in light of commenters' concerns that shortening the time period for unimproved property from six to five years would increase regulatory burden, the Board has decided to maintain the current time allowed for partial occupancy of unimproved property. Accordingly, the Board is proposing a single six-year time period for partial occupancy in this 2015 proposal. The proposed amendment therefore retains the current time period for unimproved land or unimproved real property, and extends the current time period for improved premises by three years, which the Board believes is a significant measure of relief for FCUs.

2. Waivers

Under the current rule, an FCU must submit its request for a waiver from the partial occupancy requirement within 30 months after the property is acquired. In the July 2014 proposal, the Board proposed to eliminate the 30-month requirement and allow FCUs to apply for a waiver beyond that time frame as appropriate. Seven commenters provided feedback on this aspect of the proposal, and all supported it. In light of the unanimous support from commenters on this aspect of the July 2014 proposal, the Board is restating in this 2015 proposal, without change, the proposed waiver provision originally proposed in the July 2014 proposal. Although the Board is incorporating the same proposed amendments to the partial occupancy waiver requirements, the Board still invites comments on this subject to help inform its decision for the final rule. The Board notes that it is unnecessary for commenters to the July 2014 proposal to resubmit their same comments again. NCUA has considered those previously submitted comments and will consider them again before finalizing this rule. However, commenters with new, different, or updated comments should feel free to submit them as provided for above.

3. Definition

Although the Board did not propose amending any current definitions in the fixed assets rule, five commenters expressed concern about the definition of ''partial occupancy,'' as clarified by the March 2013 proposal. Of those, four commenters suggested that the clarification reduced an FCU's ability to meet partial occupancy requirements, particularly with respect to ATMs deployed on vacant land purchased for future expansion. The commenters asked that any subsequent final rule correct this. One commenter stated generally that any subsequent final rule should reinstate the previous definition.

The Board reiterates that, as indicated in the preambles to the March 2013 proposal and the corresponding final rule,[14] the clarification of the partial occupancy definition did not impose any new regulatory requirements on FCUs or amend the meaning of that term. Rather, it only clarified the partial occupancy provisions by reflecting NCUA's interpretation of them. Accordingly, the Board is not proposing any amendments in this 2015 proposal as a result of those comments.

E. Full Occupancy

The current rule does not set a specific time period within which an FCU must achieve full occupation of premises acquired for future expansion. However, partial occupancy of the premises is required within a set timeframe and must be sufficient to show, among other things, that the FCU will fully occupy the premises within a reasonable time and consistent with its plan for the premises.[15] The Board did not propose to amend the full occupancy requirement in the July 2014 proposal, but it requested public comment on this topic.

At least four commenters said the current rule should be retained, and NCUA should not set a specific time period for full occupancy. Of those, three commenters said FCUs should have flexibility under the rule. Three commenters noted that FCU boards and management should determine the best timeframe in which to fully develop property. One commenter said there is no need to modify the full occupancy requirement, but NCUA should consider improving the definition of full occupancy.

One commenter stated generally that the full occupancy requirement should be modified and determined on a case-by-case basis. Another commenter suggested that if the requirement is modified, at a minimum, the timeframe for full occupancy should be six years for all property, along with a simple extension process. Two commenters suggested that the full occupancy requirement should be eliminated entirely. Three commenters suggested that NCUA should replace the ''full'' occupancy requirement with a ''significant'' or ''substantial'' occupancy requirement. Of these, one commenter said ''substantial occupancy'' should be defined as fifty-one percent occupancy. Another commenter suggested ''substantial occupancy'' should be defined as ''within a reasonable period of time consistent with FCU's usage plan.''

One commenter, however, argued that the full occupancy requirement should be stricter. This commenter suggested that NCUA should require full occupancy within three years of reaching partial occupancy, to ensure that FCUs are not participating in impermissible real estate activities. Citing OCC guidance, the commenter indicated that, historically, three years

Retaining a piece of property whose only purpose is to provide office space to other entities is clearly not necessary or incidental to the Federal credit union's operations. Further, investing in, or holding, property with the intent of realizing a profit from appreciation at a future sale is also outside the powers of a Federal credit union.''); 69 FR 58039, 58041 (Sept. 29, 2004) (''Federal credit unions are chartered for the purpose of providing financial services to their members and it is not permissible for them to engage in real estate activities that do not support that purpose.'')

[12] 12 CFR 701.36(b).

[13] The Board notes that a single time period would be consistent with the Office of the Comptroller of the Currency's (OCC) uniform five-year requirement for real estate acquired by banks for future expansion.

[14] 78 FR 17136 (Mar. 20, 2013); 78 FR 57250 (Sept. 18, 2013).

[15] Under the current rule, if an FCU acquires premises for future expansion and does not fully occupy them within one year, it must have an FCU board resolution in place by the end of that year with definitive plans for full occupation. 12 CFR 701.36(d)(1). The reasonableness of an FCU's plan for full occupation is evaluated through the examination process and based upon such factors as the defensibility of projection assumptions, the operational and financial feasibility of the plan, and the overall suitability of the plan relative to the FCU's field of membership.

has been a reasonable time for national banks to reach full occupancy.

The Board appreciates these comments and, after careful consideration of the points raised, it has determined to retain the current full occupancy provision. Accordingly, the Board is not proposing to amend the full occupancy requirement in this 2015 proposal. As discussed above, the limited authority in Section 107(4) the FCU Act means that an FCU may not hold real property indefinitely without fully occupying the premises. There is no authority for an FCU to invest speculatively in real estate or to otherwise engage in real estate activities that do not support its purpose of providing members with financial services. The Board reiterates there is no required time period within which an FCU must achieve full occupation. However, the limited authority for FCUs to invest in property granted by the FCU Act mandates that full occupancy must be achieved. The Board believes the current rule gives FCUs substantial flexibility in managing fixed assets acquired for future use within the authority granted in the FCU Act, and thus, no changes are proposed.

F. Leasing

At least five commenters recommended that the fixed assets rule be amended to allow an FCU to generate income from premises. Of those, three commenters urged NCUA to consider a ''de minimis ownership exception'' under which land that is not valued at more than three percent of shares and retained earnings would not be subject to the occupancy requirements. One commenter suggested that more flexibility is needed for an FCU to retain undeveloped property on a long-term basis and encouraged NCUA to allow 2.5 percent to 5 percent of an FCU's net worth to be invested in undeveloped or vacant properties. Another commenter argued that excess space should not sit idle if it could be used to generate value for the membership, even if such space is not specifically used for member business.

At least seven commenters argued that the requirement for full occupancy should allow for an FCU to lease or sublease a portion of its premises as needed. Two of these commenters argued that restrictive occupancy requirements reduce access to commercial space and limit an FCU's ability to acquire space in the most cost-effective manner. Four commenters cited a number of reasons why an FCU might want to lease its property, including zoning or retail requirements, city entitlement, or other use requirements.

Four commenters discussed credit union mergers. They suggested that, in a merger, space may be available in an existing building if operations are combined. The ability to lease or sublease this excess space could permit an FCU to realize short-term income from the lease while retaining property that fits into the FCU's long-term plans for member service. Four commenters suggested that an FCU should be allowed to maximize long-term assets, instead of avoiding reasonable acquisitions or underutilizing space to ensure compliance with occupancy requirements.

As discussed above, NCUA's long-standing interpretation is that the limited statutory authority for FCUs to invest in property mandates that full occupancy must be achieved, and there is no authority for an FCU to engage in real estate activities that do not support its purpose of providing financial services to its members. The Board has also long recognized, however, that in planning for future expansion, FCUs should be able to sell or lease their excess capacity as a matter of good business practice.[16] Indeed, the incidental powers rule permits the sale or lease of excess capacity in FCU fixed assets.[17] Excess capacity is the excess use or capacity remaining in facilities, equipment, or services that an FCU properly invested in with the good faith intent to serve its members, and where the FCU reasonably anticipates that the excess capacity will be taken up by the future expansion of services to its members.[18] An FCU's sale or lease of excess capacity may, for example, involve leasing excess office space, sharing employees, or using data processing systems to process information for third parties.[19] However, in adopting the excess capacity provision in the incidental powers rule, the Board noted in 2001 that:

> NCUA has consistently held the position that an FCU has limited authority in the leasing of fixed assets and the sale of excess data processing capacity. FCUs are not in the business of providing others with data processing capacity or any other service that is not within their express or incidental powers; rather, they are cooperative financial institutions organized to provide financial services to their members.[20]

Accordingly, the Board emphasizes that an FCU already has the authority under the incidental powers rule to obtain short-term income by leasing excess capacity in its fixed assets to third parties. However, there are limits to that authority. The fixed assets must have been acquired by an FCU, in good faith, for the purpose of providing financial services to its members, and the FCU must reasonably anticipate, and plan,[21] that the excess capacity will be fully occupied by the FCU in the future.

II. Summary of the 2015 Proposal

As discussed above, because of the public comments received in response to the July 2014 proposal, the Board is issuing this 2015 proposal to address commenters' requests for additional regulatory relief from the aggregate limit on fixed assets. The Board is also incorporating similar partial occupancy requirements from the July 2014 proposal, with one modification to the proposed single time period for partial occupancy, to provide additional relief to FCUs.

A. Aggregate Limit On Investments in Fixed Assets

Section 701.36(c) of the current fixed assets rule establishes an aggregate limit on investments in fixed assets for FCUs with $1,000,000 or more in assets.[22] For an FCU meeting this asset threshold, the aggregate of all its investments in fixed assets is limited to five percent of its shares and retained earnings, unless NCUA grants a waiver establishing a higher limit.[23] The aggregate limit is not statutorily required by the FCU Act. Rather, it was established by regulation in 1978 as a safety and soundness measure to prevent losses or impaired operations of FCUs from overinvestment in non-income producing fixed assets.[24]

In the past few years, and most recently in response to the July 2014 proposal, FCUs have asked the Board to consider increasing or eliminating the aggregate limit.[25] In addition to the

[16] 66 FR 40845, 40851 (Aug. 6, 2001).

[17] The incidental powers rule defines an incidental powers activity as one that is necessary or requisite to enable an FCU to carry on effectively the business for which it is incorporated. An activity meets the definition of an incidental powers activity if it: (1) Is convenient or useful in carrying out the mission or business of credit unions consistent with the FCU Act; (2) is the functional equivalent or logical outgrowth of activities that are part of the mission or business of credit unions; and (3) involves risks similar in nature to those already assumed as part of the business of credit unions. 12 CFR 721.2.

[18] 12 CFR 721.3(e).

[19] Id.

[20] 66 FR 40845, 40851 (Aug. 6, 2001).

[21] *See* 12 CFR 701.36(d)(1).

[22] As of September 30, 2014, 226 of the total 3,707 FCUs with assets over $1,000,000 are currently above the five percent aggregate limit.

[23] 12 CFR 701.36(c).

[24] 43 FR 58176 (Dec. 13, 1978).

[25] *See, e.g.,* 75 FR 66295, 66297 (Oct. 28, 2010); 78 FR 57250, 57250 (Sept. 18, 2013); 79 FR 46727 (Aug. 11, 2014).

comments discussed above, FCUs have repeatedly mentioned that the five percent limit is too low for FCUs to effectively manage their investments in fixed assets and to achieve growth. They have argued that the current limit does not allow FCUs adequate flexibility in acquiring fixed assets to serve their members' needs.

As discussed in the preamble to the July 2014 proposal, the objective of the fixed assets rule is to place reasonable limits on the risk associated with excessive or speculative acquisition of fixed assets.[26] Upon further review and consideration, the Board believes this objective can be effectively achieved through the supervisory process as opposed to a regulatory limit. Accordingly, the Board proposes to eliminate the five percent aggregate limit on FCU investments in fixed assets. It also proposes to eliminate the related provisions governing waivers of the aggregate limit because those provisions will no longer be necessary in the absence of a prescriptive regulatory limit.

An FCU's ability to afford a given level of fixed assets depends on a variety of factors, including its level of net worth and earnings, its operational efficiency, and risks to its future earnings and growth inherent in the FCU's balance sheet and strategic plans. Excessive levels of fixed assets can create earnings and capital accumulation problems for an FCU, and lead to greater losses to the National Credit Union Share Insurance Fund (NCUSIF), if the FCU fails and its fixed assets cannot be sold at or above their recorded value. Fixed assets not only hold member funds in non-income producing assets, but they also typically involve a material increase in FCU operating expenses, such as depreciation, maintenance, and other related expenses. According to NCUA data, excessive levels of fixed assets have contributed to the failure of some credit unions. Of the 63 FCU failures[27] that resulted in a loss to the NCUSIF since 2009, excessive levels of fixed assets contributed in part to the failures in 10 of those cases (16 percent), and were a primary contributor in 3 cases (5 percent). However, overall, excessive fixed asset levels have not been a disproportionate contributor to FCU failures. In many cases, FCUs have effectively managed elevated levels of fixed assets to safely achieve member service and growth objectives. For the 264 FCUs with fixed assets ratios exceeding five percent as of December 2004, 197 (74.62 percent) were still active as of December 2013. In comparison, the total number of credit unions from December 2004 to 2013 went from 9,128 to 6,554, representing a 71.8 percent survival rate. Thus, the level of consolidation in FCUs with elevated fixed assets levels has been no higher than for FCUs with lower levels. Also, CAMEL rating and net worth ratio distributions were not significantly different for FCUs with elevated fixed assets levels than for those without. Further, over the last 10 years, NCUA has granted approximately 500 waivers to FCUs to operate at levels of fixed assets above the five percent aggregate limit, including some above 20 percent of total assets.[28]

In addition, the experience with FCUs operating with higher fixed assets ratios under NCUA's former Regulatory Flexibility Program (RegFlex)[29] indicates that the risks associated with investment in fixed assets are manageable through supervision. Out of the 149 former RegFlex FCUs with fixed assets over the five percent aggregate limit, 120 FCUs (80 percent) were still operating nearly a decade later.[30] By comparison, as noted above, the overall survival rate for all credit unions during the same time period was 71.8 percent. Further, 25 of those 120 FCUs (20 percent) have continued to operate effectively above the five percent aggregate limit, indicating that some FCUs can safely maintain elevated levels of fixed assets over time.

Therefore, upon further analysis, the Board has determined that oversight of FCU investments in fixed assets would be effectively achieved through the supervisory process, and evaluated on a case-by-case basis. The Board emphasizes, however, that NCUA's supervisory expectations remain high. The Board cautions that the proposed elimination of the aggregate limit should not be interpreted as an invitation for FCUs to make excessive, speculative, or otherwise irresponsible investments in fixed assets. Rather, the 2015 proposal reflects the Board's recognition that relief from the prescriptive limit on fixed assets is appropriate, but FCU investments in fixed assets are, and will continue to be, subject to supervisory review. If an FCU has an elevated level of fixed assets, NCUA will maintain close oversight to ensure it conducts prudent planning and analysis with respect to fixed assets acquisitions, can afford any such acquisitions, and properly manages any ongoing risk to its earnings and capital.

If the Board finalizes this 2015 proposal, NCUA will issue updated supervisory guidance to examiners that will be shared with FCUs. The guidance will reflect current supervisory expectations[31] that require an FCU to demonstrate appropriate due diligence, ongoing board and management oversight,[32] and prudent financial analysis to ensure the FCU can afford any impact on earnings and net worth levels caused by its purchase of fixed assets. The guidance will ensure examiners effectively identify any risks to safety and soundness due to an FCU's excessive investment in fixed assets. It will focus on evaluating the quality of an FCU's fixed assets management relative to its planning for fixed assets acquisitions and controlling the related financial risks. The guidance will also focus on evaluating an FCU's quality of earnings and capital relative to its projected performance under both baseline (expected) and stressed scenarios.

B. Partial Occupancy

For the reasons discussed above, the Board is incorporating, with one change, the proposed amendments in the July 2014 proposal relating to the partial occupancy requirements for FCU premises acquired for future expansion. Specifically, the Board is proposing to require an FCU to partially occupy any premises acquired for future expansion,

[26] *See* 43 FR 26317 (June 19, 1978) (''This regulation is intended to ensure that the officials of FCUs have considered all relevant factors prior to committing large sums of members' funds to the acquisition of fixed assets.''); 49 FR 50365, 50366 (Dec. 28, 1984) (''The intent of the regulation is to prevent, or at least curb, excessive investments in fixed assets and the related costs and expenses that may be beyond the financial capability of the credit union.''); 54 FR 18466, 18467 (May 1, 1989) (''[T]he purpose of the regulation is to provide some control on the potential risk of excess investment and/or commitment to invest substantial sums in fixed assets.'').

[27] This figure includes all FCUs over $1,000,000 in assets. FCUs under that asset threshold and federally insured, state-chartered credit unions are not subject to the aggregate limit and therefore excluded from this figure.

[28] Since 2004, approximately 94 percent of waivers were for levels of fixed assets less than 10 percent of total assets.

[29] The RegFlex Program was established in 2002, 66 FR 58656 (Nov. 23, 2001), and eliminated in 2012, 77 FR 31981 (May 31, 2012). RegFlex relieved FCUs from certain regulatory restrictions and granted them additional powers if they demonstrated sustained superior performance as measured by CAMEL ratings and net worth classification. One of the flexibilities enjoyed by RegFlex FCUs at one time was relief from the aggregate limit on fixed assets.

[30] As of December 31, 2013, in 95 of those 120 FCU (80 percent), fixed assets levels had declined to under 5 percent.

[31] *See* NCUA Examiner's Guide, Chapter 8.

[32] The credit union's board needs to approve plans for any investment in fixed assets that will materially affect the credit union's earnings. Credit union management should only purchase fixed assets in compliance with policy approved by the credit union's board.

regardless of whether the premises are improved or unimproved property, within six years from the date of the FCU's acquisition of those premises. In the July 2014 proposal, the Board had proposed to require partial occupancy within a uniform five years. However, as discussed above, in response to public comments, this 2015 proposal provides six years rather than five years for partial occupancy, which retains the current time period for unimproved land or unimproved real property and extends the current time period for improved premises by three years. In addition, the Board is reissuing in this 2015 proposal, without change, the amendment in the July 2014 proposal to eliminate the requirement that an FCU that wishes to apply for a waiver of the partial occupancy requirement must do so within 30 months of acquisition of the property acquired for future expansion.

C. Conforming Amendments

The Board is also proposing to make conforming amendments to the fixed assets rule's scope and definitions sections. Specifically, the Board proposes to amend § 701.36(a) of the current fixed assets rule to remove reference to the aggregate limit on FCU investments in fixed assets. This language is unnecessary with the proposed removal of the aggregate limit. This 2015 proposal also amends § 701.36(b) of the current fixed assets rule to remove the regulatory definitions of the following terms: ''fixed assets,'' ''furniture, fixtures, and equipment,'' ''investments in fixed assets,'' ''retained earnings,'' and ''shares.'' These definitions are included in the current rule to provide meaning to certain terms used in the regulatory provision establishing the aggregate limit on fixed assets. With the proposed removal of the aggregate limit, however, inclusion of these regulatory definitions is no longer necessary.

D. Amended Title

Finally, the Board proposes to amend the title of the regulation to more accurately reflect its amended scope and applicability. Currently, the rule is titled ''Federal credit union ownership of fixed assets.'' If the 2015 proposal is finalized, the rule will be retitled ''Federal credit union occupancy, planning, and disposal of acquired and abandoned premises.''

E. Effect on Existing Waivers

Should the 2015 proposal become finalized as proposed, any existing waiver of the five percent aggregate limit on fixed assets will be rendered moot as of the effective date of the final rule.

III. Request for Public Comment

Because the proposed amendments are intended to grant regulatory relief to FCUs, and the Board perceives no reason to delay their implementation, the Board is issuing the 2015 proposal for a 30-day public comment period instead of NCUA's customary 60 days. Additionally, the Board already solicited comments on this subject in the July 2014 proposal. The Board invites comment on all issues discussed in this 2015 proposal; however, as noted earlier, it is not necessary for commenters to resubmit any comments they previously submitted in response to the July 2014 proposal. NCUA has already reviewed those comments and will consider them again before finalizing this rule.

IV. Regulatory Procedures

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that, in connection with a notice of proposed rulemaking, an agency prepare and make available for public comment an initial regulatory flexibility analysis that describes the impact of a proposed rule on small entities. A regulatory flexibility analysis is not required, however, if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities (defined for purposes of the RFA to include credit unions with assets less than $50 million) and publishes its certification and a short, explanatory statement in the **Federal Register** together with the rule. The 2015 proposal would provide regulatory relief to help FCUs better manage their investments in fixed assets. NCUA certifies that the 2015 proposal will not have a significant economic impact on a substantial number of small credit unions.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) applies to rulemakings in which an agency by rule creates a new paperwork burden on regulated entities or modifies an existing burden.[33] For purposes of the PRA, a paperwork burden may take the form of either a reporting or a recordkeeping requirement, both referred to as information collections. The 2015 proposal provides regulatory relief to FCUs by eliminating the requirement that, for an FCU with $1,000,000 or more in assets, the aggregate of all its investments in fixed assets must not exceed five percent of its shares and retained earnings, unless it obtains a waiver from NCUA. The 2015 proposal does not impose new paperwork burdens. However, the 2015 proposal would relieve FCUs from the current requirement to obtain a waiver to exceed the five percent aggregate limit on investments in fixed assets.

According to NCUA records, as of September 30, 2014, there were 3,707 FCUs with assets over $1,000,000 and subject to the five percent aggregate limit on fixed assets. Of those, approximately 150 FCUs would prepare and file a new waiver request to exceed the five percent aggregate limit. This effort, which is estimated to create 15 hours burden per waiver, would no longer be required under the 2015 proposal. Accordingly, the reduction to existing paperwork burdens that would result from the 2015 proposal is analyzed below:

Estimate of the Reduced Burden by Eliminating the Waiver Requirement

Estimated FCUs which will no longer be required to prepare a waiver request and file a waiver request: 150.

Frequency of waiver request: Annual.

Reduced hour burden: 15.

150 FCUs × 15 hours = 2250 hours annual reduced burden

In accordance with the requirements of the PRA, NCUA intends to obtain a modification of its OMB Control Number, 3133–0040, to support these changes. NCUA is submitting a copy of the 2015 proposal to OMB, along with an application for a modification of the OMB Control Number.

The PRA and OMB regulations require that the public be provided an opportunity to comment on the paperwork requirements, including an agency's estimate of the burden of the paperwork requirements. The Board invites comment on: (1) Whether the paperwork requirements are necessary; (2) the accuracy of NCUA's estimates on the burden of the paperwork requirements; (3) ways to enhance the quality, utility, and clarity of the paperwork requirements; and (4) ways to minimize the burden of the paperwork requirements.

Comments should be sent to the NCUA Contact and the OMB Reviewer listed below:

NCUA Contact: Amanda Wallace, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: *OCIOPRA@ncua.gov.*

OMB Contact: Office of Management and Budget, ATTN: Desk Officer for the

[33] 44 U.S.C. 3507(d); 5 CFR part 1320.

National Credit Union Administration, Office of Information and Regulatory Affairs, Washington, DC 20503.

C. Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. NCUA, an independent regulatory agency, as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order to adhere to fundamental federalism principles. Because the fixed assets regulation applies only to FCUs, the 2015 proposal 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. As such, NCUA has determined that this rule does not constitute a policy that has federalism implications for purposes of the executive order.

D. Assessment of Federal Regulations and Policies on Families

NCUA has determined that this rule will not affect family well-being within the meaning of Section 654 of the Treasury and General Government Appropriations Act of 1999.[34]

List of Subjects in 12 CFR Part 701

Credit unions, Reporting and recordkeeping requirements.

By the National Credit Union Administration Board, on March 19, 2015.

Gerard Poliquin,

Secretary of the Board.

For the reasons stated above, NCUA proposes to amend 12 CFR 701.36 as follows:

PART 701—ORGANIZATION AND OPERATION OF FEDERAL CREDIT

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

Authority: 12 U.S.C. 1752(5), 1757, 1765, 1757, 1758, 1759, 1761a, 1761b, 1766, 1767, 1782, 1784, 1786, 1787, 1789. Section 701.6 is also authorized by 15 U.S.C. 3717. Section 701.31 is also authorized by 15 U.S.C. 1601 *et seq.;* 42 U.S.C. 1981 and 3601–3610. Section 701.35 is also authorized by 42 U.S.C. 4311–4312.

■ 2. In § 701.36 revise the section heading and paragraph (a) to read as follows:

§ 701.36 Federal credit union occupancy, planning, and disposal of acquired and abandoned premises.

(a) *Scope.* Section 107(4) of the Federal Credit Union Act (12 U.S.C. 1757(4)) authorizes a federal credit union to purchase, hold, and dispose of property necessary or incidental to its operations. This section interprets and implements that provision by establishing occupancy, planning, and disposal requirements for acquired and abandoned premises, and by prohibiting certain transactions.

This section applies only to federal credit unions.

* * * * *

■ 3. Revise § 701.36 paragraph (b) by removing the following definitions: ''fixed assets'', ''furniture, fixtures, and equipment'', ''investments in fixed assets'', ''retained earnings'', and ''shares''.

■ 4. Remove § 701.36 paragraph (c).

■ 5. Revise § 701.36 paragraph (d)(2) to read as follows:

(d) * * *

(2) If a federal credit union acquires premises for future expansion, including unimproved land or unimproved real property, it must partially occupy them within a reasonable period, but no later than six years after the date of acquisition. NCUA may waive the partial occupation requirements. To seek a waiver, a federal credit union must submit a written request to its Regional Office and fully explain why it needs the waiver. The Regional Director will provide the federal credit union a written response, either approving or disapproving the request. The Regional Director's decision will be based on safety and soundness considerations.

* * * * *

■ 6. In § 701.36 redesignate paragraph (d) as paragraph (c) and paragraph (e) as paragraph (d).

[FR Doc. 2015–06816 Filed 3–27–15; 8:45 am]

BILLING CODE 7535–01–P

[34] Public Law 105–277, 112 Stat. 2681 (1998).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–0674; Directorate Identifier 2014–SW–019–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters Deutschland GmbH (Previously Eurocopter Deutschland GmbH) Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede airworthiness directive (AD) 2014–05–06 for certain Eurocopter Deutschland GmbH (ECD) (now Airbus Helicopters Deutschland GmbH) Model EC135 and MBB–BK 117 C–2 helicopters to correct an error. AD 2014–05–06 currently requires inspecting the flight-control bearings repetitively, replacing any loose bearing with an airworthy flight-control bearing, and installing bushings and washers. This proposed AD would require the same actions. This proposed AD results from the discovery of an error in the compliance time for AD 2014–05–06. These proposed actions are intended to prevent the affected control lever from shifting, contacting the helicopter structure, and reducing control of the helicopter.

DATES: We must receive comments on this proposed AD by May 29, 2015.

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

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the European Aviation Safety Agency

(EASA) AD, the economic evaluation, any comments received and other information. The street address for the Docket Operations Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this proposed AD, contact Airbus Helicopters, Inc., 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *http://www.airbushelicopters.com/techpub.* You may review service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0674.

FOR FURTHER INFORMATION CONTACT: Matt Fuller, Senior Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5110; email *matthew.fuller@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

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

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

Discussion

On February 20, 2014, we issued AD 2014–05–06, Amendment 39–17779 (79 FR 13196, March 10, 2014), for certain ECD (now Airbus Helicopters Deutschland GmbH) Model EC135 and MBB–BK 117 C–2 helicopters. AD 2014–05–06 requires inspecting the flight-control bearings repetitively, replacing any loose bearing with an airworthy flight-control bearing, and installing bushings and washers. AD 2014–05–06 was prompted by the discovery of loose flight control bearings because of incorrect installation. This condition, if not corrected, could result in the affected control lever shifting, contacting the helicopter structure, and reducing control of the helicopter.

Actions Since AD 2014–05–06 Was Issued

Since we issued AD 2014–05–06 (79 FR 13196, March 10, 2014), we discovered an error regarding the compliance time for certain model helicopters. Paragraph (e)(1)(i) should have required that certain actions be accomplished within the next 100 hours time-in-service or at the next annual inspection, whichever occurs first. However, we omitted the word ''first'' from that sentence, which changes the meaning of the required compliance time.

Also since we issued AD 2014–05–06, ECD changed its name to Airbus Helicopters Deutschland GmbH. This proposed AD reflects that change and updates the contact information to obtain service documentation.

FAA's Determination

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

Related Service Information Under 1 CFR Part 51

ECD, now called Airbus Helicopters, has issued Alert Service Bulletin (ASB) MBB BK117 C–2–67A–010, Revision 3, dated February 8, 2010, and ASB EC135–67A–019, Revision 3, dated December 16, 2009. These ASBs specify:

- Within the next 50 flight hours (FHs), inspecting the affected bearings and, if necessary, rebonding any affected bearings or replacing the lever assembly.
- Within 12 months, retrofitting bushings and washers on the levers to prevent movement of the bearings.
- After the retrofit, repeating the inspection every 800 FHs or 36 months for the Model EC135 helicopters, whichever comes first, and 600 FHs or 24 months, whichever comes first, for the Model MBB–BK 117 C–2 helicopters.

EASA classified these ASBs as mandatory and issued AD No. 2010–0058 to ensure the continued airworthiness of these helicopters. 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 NPRM.

Proposed AD Requirements

For Airbus Model EC135 P1, P2, P2+, T1, T2, and T2+ helicopters this proposed AD would require:

- Within the next 100 hours time-in-service (TIS) or at the next annual inspection, whichever occurs first, modifying the left-hand (LH) and right-hand (RH) guidance units and the cyclic shaft by installing bushings and washers to prevent shifting of the bearings in the axial direction.
- At intervals not to exceed 800 hours TIS or 36 months, whichever occurs first, inspecting the bearings in the LH guidance unit, RH guidance unit, cyclic control, upper guidance unit, and linear voltage differential transducer plate for play. If any bearing is loose, replacing the affected bearing with an airworthy bearing.

For Model MBB–BK 117 C–2 helicopters, this proposed AD would require:

- Within the next 100 hours TIS or at the next annual inspection, whichever occurs first, modifying the LH and RH guidance units and the lateral control lever by installing bushings and washers to prevent shifting of the bearings in the axial direction.
- At intervals not to exceed 600 hours TIS or 24 months, whichever occurs first, inspecting the bearings in the RH guidance unit, LH guidance unit, and lateral control guidance unit for play. If any bearing is loose, replacing the affected bearing with an airworthy bearing.

Differences Between This Proposed AD and the EASA AD

Differences between this proposed AD and the EASA AD are:

- The EASA AD is applicable to the EC 635 helicopter, whereas this proposed AD is not because the EC 635 helicopter is not type certificated in the U.S.
- The EASA AD requires an initial inspection within 50 flight hours or one

month, whichever occurs first after May 31, 2008, and a modification within the next 12 months. This proposed AD would require the modification within 100 hours TIS or at the next annual inspection, whichever occurs first, and no inspection until after the modification has been accomplished.

• The EASA AD applies to all EC135 and MBB–BK 117 C–2 helicopters, while this proposed AD would apply to certain serial-numbered Model EC135 and Model MBB–BK 117 C–2 helicopters, as recommended by the appropriate ECD ASB.

Costs of Compliance

We estimate that this proposed AD would affect 175 Model EC135 and 112 Model MBB–BK 117 C–2 helicopters of U.S. Registry and that labor costs would average $85 per work-hour. Based on these estimates, we expect the following costs:

• For EC135 helicopters, it would take about 32 work-hours to perform the modification. Parts would cost about $312. The total cost for the modification would be about $3,032 per helicopter and $530,600 for the U.S. operator fleet. The repetitive inspections would require 6.5 work-hours for a cost of about $553 per helicopter and about $96,775 for the fleet per inspection cycle.

• For MBB–BK 117 C–2 helicopters, it would take about 32 work-hours to perform the modification. Parts would cost about $396. The total cost for the modification would be $3,116 per helicopter and $348,992 for the U.S. operator fleet. The cost for the repetitive inspections thereafter would be about $85 per helicopter and $9,520 for the fleet per inspection cycle.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed, I certify this proposed regulation:

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2014–05–06, Amendment 39–17779 (79 FR 13196, March 10, 2014), and adding the following new AD:

Airbus Helicopters Deutschland GmbH (Previously Eurocopter Deutschland GmbH): Docket No. FAA–2015–0674; Directorate Identifier 2014–SW–019–AD.

(a) Applicability

This AD applies to the following helicopters, certificated in any category:

(1) Model EC135 P1, P2, P2+, T1, T2, and T2+ helicopters, serial number (S/N) 0005 through 00829, with a tail rotor control lever, part number (P/N) L672M2802205 or L672M1012212; cyclic control lever, P/N L671M1005250; collective control lever assembly, P/N L671M2020108; or collective control plate, P/N L671M5040207; installed; and

(2) Model MBB–BK 117 C–2 helicopters, S/N 9004 through 9310, with a tail rotor control lever assembly, P/N B672M1007101 or B672M1807101; tail rotor control lever, P/N B672M1002202 or L672M2802205; or lateral control lever assembly, P/N B670M1008101, installed.

(b) Unsafe Condition

This AD defines the unsafe condition as incorrectly installed flight control bearings. This condition could cause the affected control lever to shift and contact the helicopter structure, resulting in reduced control of the helicopter.

(c) Affected ADs

This AD supersedes AD 2014–05–06, Amendment 39–17779 (79 FR 13196, March 10, 2014).

(d) Comments Due Date

We must receive comments by May 29, 2015.

(e) Compliance

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

(f) Required Actions

(1) For Model EC135 P1, P2, P2+, T1, T2, and T2+ helicopters:

(i) Within the next 100 hours time-in-service (TIS) or at the next annual inspection, whichever occurs first, modify the left-hand (LH) and right-hand (RH) guidance units and the cyclic shaft by installing bushings and washers to prevent shifting of the bearings in the axial direction as follows:

(A) Remove and disassemble the LH guidance unit and install a bushing, P/N L672M1012260, between the bearing block and the lever of the LH guidance unit as depicted in Detail A of Figure 5 of Eurocopter Alert Service Bulletin EC135–67A–019, Revision 3, dated December 16, 2009 (EC135 ASB).

(B) For helicopters without a yaw brake, remove and disassemble the RH guidance unit and install a bushing, P/N L672M1012260, between the bearing block and the lever as depicted in Detail B of Figure 5 of EC135 ASB.

(C) Remove and disassemble the cyclic shaft and install a washer, P/N L671M1005260, between the bearing block and the lever as depicted in Detail C of Figure 6 of EC135 ASB.

(D) Remove the collective control rod from the bellcrank and install a washer, P/N L221M1042208, on each side of the collective control rod and bellcrank as depicted in Detail D of Figure 6 of EC135 ASB.

(E) At intervals not to exceed 800 hours TIS or 36 months, whichever occurs first, inspect the bearings in the LH guidance unit, RH guidance unit, cyclic control, upper guidance unit, and linear voltage differential transducer plate for play. If any bearing is

loose, replace the affected bearing with an airworthy bearing.

(2) For Model MBB–BK 117 C–2 helicopters:

(i) Within the next 100 hours TIS or at the next annual inspection, whichever occurs first, modify the LH and RH guidance units and the lateral control lever by installing bushings and washers to prevent shifting of the bearings in the axial direction as follows:

(A) Remove and disassemble the RH guidance unit and install a bushing, P/N L672M1012260, between the lever and the bracket as depicted in Detail B of Figure 4 of Eurocopter Alert Service Bulletin MBB BK117 C–2–67A–010, Revision 3, dated February 8, 2010 (BK117 ASB). Remove and disassemble the LH guidance unit and install a bushing, P/N L672M1012260, between the lever and the bracket as depicted in Detail C of Figure 4 of BK117 ASB.

(B) Remove the lateral control lever and install new bushings in accordance with the Accomplishment Instructions, paragraphs 3.C(9)(a) through 3.C(9)(g), of BK 117 ASB.

(C) Identify the modified lever assembly by writing ''MBB BK117 C–2–67A–010'' on the lever with permanent marking pen and protect with a single layer of lacquer (CM 421 or equivalent).

(D) Apply corrosion preventive paste (CM 518 or equivalent) on the shank of the screws and install airworthy parts as depicted in Figure 5 of BK117 ASB.

(E) At intervals not to exceed 600 hours TIS or 24 months, whichever occurs first, inspect the bearings in the RH guidance unit, LH guidance unit, and lateral control guidance unit for play. If any bearing is loose, replace the affected bearing with an airworthy bearing.

(g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Matt Fuller, Senior Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5110; email *matthew.fuller@faa.gov.*

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

(h) Additional Information

The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. 2010–0058, dated March 30, 2010. You may view the EASA AD on the Internet at *http://www.regulations.gov* in Docket No. FAA–2015–0674.

(i) Subject

Joint Aircraft Service Component (JASC) Code: 6710, Main Rotor Control.

Issued in Fort Worth, Texas, on March 18, 2015.

Lance T. Gant,

Acting Directorate Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2015–06806 Filed 3–27–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–0498; Directorate Identifier 2014–NM–152–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 2007–16–08, which applies to all The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–300, 747–400, 747–400D, and 747SR series airplanes. AD 2007–16–08 currently requires repetitive inspections for cracking of the station 800 frame assembly, and repair if necessary. Since we issued AD 2007–16–08, we have received additional reports of cracks found at the forward and aft inner chord strap and angles on the station 800 frame on the left-side and right-side main entry doors. This proposed AD would expand the inspection area. We are proposing this AD to detect and correct fatigue cracks that could extend and fully sever the frame, which could result in development of skin cracks that could lead to rapid depressurization of the airplane.

DATES: We must receive comments on this proposed AD by May 14, 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 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. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0498.

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–2015–0498; 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: Bill Ashforth, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6432; fax: 425–917–6590; email: *bill.ashforth@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2015–0498; Directorate Identifier 2014–NM–152–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

On July 30, 2007, we issued AD 2007–16–08, Amendment 39–15147 (72 FR 44728, August 9, 2007), for all The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–300, 747–400, 747–400D, and 747SR series airplanes. AD 2007–16–08 requires repetitive inspections for cracking of the station 800 frame assembly, and repair if necessary. AD 2007–16–08 resulted from several reports of cracks of the station 800 frame assembly on airplanes that occurred sooner than previously anticipated. We issued AD 2007–16–08 to detect and correct fatigue cracks that could extend and fully sever the frame, which could result in development of skin cracks that could lead to rapid depressurization of the airplane.

Actions Since AD 2007–16–08, Amendment 39–15147 (72 FR 44728, August 9, 2007), Was Issued

Since we issued AD 2007–16–08, Amendment 39–15147 (72 FR 44728, August 9, 2007), we received additional reports of cracking found at the forward and aft inner chord strap and angles on the station 800 frame on the left-side and right-side main entry doors. These cracks are outside the inspection area of AD 2007–16–08. We have determined that additional inspections are needed. This proposed AD would expand the inspection area to include the station 800 frame between stringer 18 and stringer 30.

Related Service Information Under 1 CFR part 51

We reviewed Boeing Alert Service Bulletin 747–53A2451, Revision 2, dated June 13, 2014. The service information describes procedure for inspecting and repairing cracking of the door number 2 forward edge frame assembly at body station 800. Refer to this service information for information on the procedures and compliance times. 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

Although this proposed AD does not explicitly restate the requirements of AD 2007–16–08, Amendment 39–15147 (72 FR 44728, August 9, 2007), this proposed AD would retain certain requirements of AD 2007–16–08. Those requirements are referenced in the service information identified previously, which, in turn, is referenced in paragraphs (g) and (h) of this proposed AD. This proposed AD would require additional inspections. This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed under ''Differences Between this Proposed AD and the Service Information.''

Differences Between This Proposed AD and the Service Information

Where Boeing Alert Service Bulletin 747–53A2451, Revision 2, dated June 13, 2014, specifies to contact the manufacturer for instructions on how to repair certain conditions, this proposed AD would require repairing those conditions in one of the following ways:

- In accordance with a method that we approve; or
- Using data that meet the certification basis of the airplane, and that have been approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) whom we have authorized to make those findings.

Costs of Compliance

We estimate that this proposed AD affects 124 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Repetitive inspections.	Up to 53 work-hours × $85 per hour = $4,505 per inspection cycle.	$0	Up to $4,505 per inspection cycle.	Up to $558,620 per inspection cycle

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this proposed AD.

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 have 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 that the proposed regulation:

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2007–16–08, Amendment 39–15147 (72 FR 44728, August 9, 2007), and adding the following new AD:

The Boeing Company: Docket No. FAA–2015–0498; Directorate Identifier 2014–NM–152–AD.

(a) Comments Due Date

The FAA must receive comments on this AD action by May 14, 2015.

(b) Affected ADs

This AD replaces AD 2007–16–08, Amendment 39–15147 (72 FR 44728, August 9, 2007).

(c) Applicability

This AD applies to all Boeing Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–300, 747–400, 747–400D, and 747SR series airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by reports of cracks found on the station 800 frame on the left-side and right-side main entry doors (MED), at the forward and aft inner chord strap and angles, which are outside the inspection area of AD 2007–16–08, Amendment 39–15147 (72 FR 44728, August 9, 2007). We are issuing this AD to detect and correct fatigue cracks that could extend and fully sever the frame, which could result in development of skin cracks that could lead to rapid depressurization of the airplane.

(f) Compliance

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

(g) Inspections of Station 800 Frame Assembly Between Stringer 14 and Stringer 30

Except as required by paragraph (i) of this AD, at the applicable time specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 747–53A2451, Revision 2, dated June 13, 2014: Do a detailed inspection for cracking in the inner chord strap, angles, and exposed web adjacent to the inner chords, and do surface and open hole high-frequency eddy current (HFEC) inspections for cracking in the inner chord strap and angles of the station 800 frame assembly between stringer 14 and stringer 30, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 747–53A2451, Revision 2, dated June 13, 2014. Repeat the inspections at the applicable times specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 747–53A2451, Revision 2, dated June 13, 2014.

(h) Repair of Cracking

If any cracking is found during any inspection required by paragraph (g) of this AD, before further flight, repair the cracking using a method approved in accordance with the procedures specified in paragraph (k) of this AD.

(i) Exception to the Service Information

(1) Where Boeing Alert Service Bulletin 747–53A2451, Revision 2, dated June 13, 2014, specifies a compliance time ''after the Revision 2 date of this service bulletin,'' this AD requires compliance within the specified time after the effective date of this AD.

(2) The Condition column of paragraph 1.E., ''Compliance,'' of the Boeing Alert Service Bulletin 747–53A2451, Revision 2, dated June 13, 2014, refers to total flight cycles ''as of the Revision 2 date of this service bulletin.'' This AD, however applies to airplanes with the specified total flight cycles or total flight hours as of the effective date of this AD.

(j) Credit for Previous Actions

This paragraph provides credit for the inspections and repairs of the inner chord strap and angles of the station 800 frame assembly between stringer 14 and stringer 18 required by paragraphs (g) and (h) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Service Bulletin 747–53A2451, Revision 1, dated November 10, 2005.

(k) 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) AMOCs approved for AD 2007–16–08, Amendment 39–15147 (72 FR 44728, August 9, 2007), are approved as AMOCs for the corresponding provisions of this AD.

(l) Related Information

(1) For more information about this AD, contact Bill Ashforth, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6432; fax: 425–917–6590; email: *bill.ashforth@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.

Issued in Renton, Washington, on March 19, 2015.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–07081 Filed 3–27–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–0676; Directorate Identifier 2014–NM–164–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Bombardier, Inc. Model BD–700–1A10 and BD–700–1A11 airplanes. This proposed AD was prompted by a report of several events where pilots experienced difficulty in lateral control of the airplane after doing a climb through heavy rain conditions and a determination that the cause was water ingress in the aileron control pulley assembly. This proposed AD would require, for certain airplanes, inspecting for correct clearance and rework if necessary, and, for certain other airplanes, installing a cover for the aileron pulley assembly. We are proposing this AD to prevent water ingress in the aileron control pulley assembly, which could freeze in cold conditions and result in reduced control of the airplane.

DATES: We must receive comments on this proposed AD by May 14, 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:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.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.

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–2015–0676; 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 Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Fabio Buttitta, Aerospace Engineer, Airframe and Mechanical Systems Branch, ANE–171, FAA, New York Aircraft Certification Office (ACO), 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7303; fax 516–794–5531.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2015–0676; Directorate Identifier 2014–NM–164–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

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

Discussion

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF–2014–23, dated July 18, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Bombardier, Inc. Model BD–700–1A10 and BD–700–1A11 airplanes. The MCAI states:

> There have been several reports whereby pilots have experienced difficulty in lateral control following climb through heavy rain conditions. In each event, the pilots were able to overcome this difficulty without disconnecting the aileron control. An investigation has determined that the root cause of the restricted movement of the aileron was due to water ingress into the wing root aileron control pulley assembly through a gap on the wing-to-fuselage fairing resulting in freezing of the aileron control system.
>
> If not corrected, this condition could result in reduced lateral control of the aeroplane.
>
> This [Canadian] AD mandates [for certain airplanes] the incorporation of a cover for the aileron pulley assembly [and inspection and rework if necessary] to prevent water ingress in the aileron control pulley assembly [and for certain other airplanes, mandates an inspection and rework if necessary].

The inspection involves doing a general visual inspection for correct clearance. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0676.

Related Service Information Under 1 CFR Part 51

Bombardier has issued the following service information:

- Service Bulletin 700–1A11–27–034, Revision 04, dated September 4, 2014;
- Service Bulletin 700–27–076, Revision 04, dated September 4, 2014;
- Service Bulletin 700–27–5004, Revision 04, dated September 4, 2014; and
- Service Bulletin 700–27–6004, Revision 04, dated September 4, 2014.

This service information describes procedures, for certain airplanes, for installing a cover for the No. 1 aileron pulley, including an inspection for correct clearance and rework, and for certain other airplanes, for an inspection for correct clearance and rework. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI. This service information is reasonably available; see **ADDRESSES** for ways to access this service information.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

We estimate that this proposed AD affects 60 airplanes of U.S. registry.

We also estimate that it would take about 9 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $45,900, or $765 per product.

According to the manufacturer, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for

safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

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

1. Is not a ''significant regulatory action'' under Executive Order 12866;
2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Bombardier, Inc.: Docket No. FAA–2015–0676; Directorate Identifier 2014–NM–164–AD.

(a) Comments Due Date

We must receive comments by May 14, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc. Model BD–700–1A10 and BD–700–1A11 airplanes, certificated in any category, having serial numbers 9002 through 9520 inclusive and 9998.

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight Controls.

(e) Reason

This AD was prompted by a report of several events where pilots experienced difficulty in lateral control of the airplane after doing a climb through heavy rain conditions and a determination that the cause was water ingress in the aileron control pulley assembly. We are issuing this AD to prevent water ingress in the aileron control pulley assembly, which could freeze in cold conditions and result in reduced control of the airplane.

(f) Compliance

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

(g) Installation of Cover for the Aileron Pulley Assembly

Except as provided by paragraph (j) of this AD, for airplanes on which a cover for the No. 1 aileron pulley was not installed as of the effective date of this AD: Within 150 flight cycles after the effective date of this AD, install a cover for the No. 1 aileron pulley, including doing a general visual inspection for correct clearance and rework as applicable, in accordance with paragraph C., ''PART B—Modification,'' of the Accomplishment Instructions of the applicable service bulletins identified in paragraphs (g)(1) and (g)(2) for this AD.

(1) For Model BD–700–1A10 airplanes: Bombardier Service Bulletin 700–27–076, Revision 04, dated September 4, 2014; or 700–27–6004, Revision 04, dated September 4, 2014.

(2) For Model BD–700–1A11 airplanes: Bombardier Service Bulletin 700–1A11–27–034, Revision 04, dated September 4, 2014; or 700–27–5004, Revision 04, dated September 4, 2014.

(h) Inspection and Rework

Except as provided by paragraph (j) of this AD, for airplanes that have incorporated a cover for the No. 1 aileron pulley using the applicable service information identified in paragraphs (h)(1) and (h)(2) of this AD as of the effective date of this AD: Within 150 flight cycles after the effective date of this AD, do a general visual inspection for correct clearance and, before further flight, rework, as applicable, in accordance with paragraph B., ''PART A—Inspection and Rework,'' of the Accomplishment Instructions of the applicable service information identified in paragraphs (g)(1) and (g)(2) of this AD.

(1) For Model BD–700–1A10 airplanes: Bombardier Service Bulletin 700–27–076, dated March 5, 2012; or 700–27–6004, dated March 5, 2012.

(2) For Model BD–700–1A11 airplanes: Bombardier Service Bulletin 700–1A11–27–034, dated March 5, 2012; or 700–27–5004, dated March 5, 2012.

(i) Re-Identification of Overwing Panels

Except as provided by paragraph (j) of this AD, for airplanes on which the Service Non-Incorporated Engineering Orders (SNIEO) or Service Requests for Product Support Action (SRPSA) that are listed in table 2 of paragraph 1.A., ''Effectivity,'' in the service information identified in paragraphs (i)(1), (i)(2), or (i)(3) of this AD have been incorporated: Within 150 flight cycles from the effective date of this AD, do the re-identification of the overwing panels, in accordance with paragraph 2.B(2)(g) of the Accomplishment Instructions of the applicable service information identified in paragraphs (g)(1) and (g)(2) of this AD.

(1) Bombardier Service Bulletin 700–27–076, Revision 04, dated September 4, 2014.

(2) Bombardier Service Bulletin 700–27–6004, Revision 04, dated September 4, 2014.

(3) Bombardier Service Bulletin 700–1A11–27–034, Revision 04, dated September 4, 2014.

(j) Exception to the Requirements of Paragraphs (g), (h), and (i) of this AD

Airplanes on which the SRPSA, as listed in table 1 of paragraph 1.A., ''Effectivity,'' in the service information identified in paragraph (j)(1), (j)(2), or (j)(3) of this AD has been accomplished as of the effective date of this AD, meet the intent of paragraphs (g), (h), and (i) of this AD and no further action is required.

(1) Bombardier Service Bulletin 700–27–076, Revision 04, dated September 4, 2014.

(2) Bombardier Service Bulletin 700–27–6004, Revision 04, dated September 4, 2014.

(3) Bombardier Service Bulletin 700–1A11–27–034, Revision 04, dated September 4, 2014.

(k) Credit for Previous Actions

This paragraph provides credit for actions required by paragraphs (g), (h), and (i) of this AD, if those actions were performed before the effective date of this AD using the applicable service information identified in paragraphs (k)(1) through (k)(8) of this AD, which are not incorporated by reference in this AD.

(1) Bombardier Service Bulletin 700–1A11–27–034, Revision 01, dated July 16, 2012.

(2) Bombardier Service Bulletin 700–1A11–27–034, Revision 02, dated June 17, 2014.

(3) Bombardier Service Bulletin 700–27–076, Revision 01, dated July 16, 2012.

(4) Bombardier Service Bulletin 700–27–076, Revision 02, dated June 17, 2014.

(5) Bombardier Service Bulletin 700–27–5004, Revision 01, dated July 16, 2012.

(6) Bombardier Service Bulletin 700–27–5004, Revision 02, dated June 17, 2014.

(7) Bombardier Service Bulletin 700–27–6004, Revision 01, dated July 16, 2012.

(8) Bombardier Service Bulletin 700–27–6004, Revision 02, dated June 17, 2014.

(l) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York Aircraft Certification Office (ACO), ANE–170, 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 ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/ certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO, ANE–170, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(m) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian Airworthiness Directive CF–2014–23, dated July 18, 2014, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0676.

(2) For service information identified in this AD, contact Bombardier, Inc., 400 Côte Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com.* 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.

Issued in Renton, Washington, on March 19, 2015.

Michael Kaszyscki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–07072 Filed 3–27–15; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2015–0170; FRL–9925–23–Region 7]

Approval and Promulgation of Implementation Plans; State of Missouri, Control of Sulfur Emissions From Stationary Boilers

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve an amendment to the State Implementation Plan (SIP) submitted by the State of Missouri on October 17, 2013, related to the Missouri rule ''Control of Sulfur Emissions from Stationary Boilers.'' The SIP revision is administrative and provides clarity on the applicability of emission limits and removes definitions originally included in this rule which have been moved to the ''Definitions and Common Reference Tables'' rule.

DATES: Comments on this proposed action must be received in writing by April 29, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2015–0170, by mail to Larry Gonzalez, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Larry Gonzalez, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at 913–551–7041, or by email at *gonzalez.larry@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA is proposing to approve an amendment to the SIP submitted by the State of Missouri on October 17, 2013, related to Missouri rule 10 CSR 10–5.570 ''Control of Sulfur Emissions from Stationary Boilers.'' The SIP revision is administrative and provides clarity on the applicability of emission limits specified at 10 CSR 10–5.570(3)(A)2. Additionally, the amendment removes definitions originally included in 10 CSR 10–5.570 which have been moved to 10 CSR 10.6.020 ''Definitions and Common Reference Tables''.

In the final rules section of the **Federal Register**, EPA is approving the state's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no relevant adverse comments to this action. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action, no further activity is contemplated in relation to this action. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed action. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on part of this rule and if that part can be severed from the remainder of the rule, EPA may adopt as final those parts of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the rules section of this **Federal Register**.

List of Subjects in 40 CFR Part 52

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

Dated: March 17, 2015.

Mark Hague,

Acting Regional Administrator, Region 7.

[FR Doc. 2015–07125 Filed 3–27–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2015–0033; FRL–9925–20–Region 6]

Approval and Promulgation of Implementation Plans; Texas; Public Participation for Air Quality Permit Applications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve two provisions submitted by the State of Texas as revisions to the Texas State Implementation Plan (SIP) on July 2, 2010, specific to the applicability of the public notice requirements to applications for Plant-Wide Applicability (PAL) permits and standard permits for concrete batch plants without enhanced controls. Today's proposal and the accompanying direct final action will complete the rulemaking process started in our December 13, 2012, proposal and approve the public notice provisions into the Texas SIP. The EPA is proposing to convert the public notice applicability provisions for Texas Flexible Permits from a final conditional approval to a full approval. The EPA is proposing approval of these revisions

pursuant to section 110 and parts C and D of the Federal Clean Air Act.

DATES: Written comments should be received on or before April 29, 2015.

ADDRESSES: Comments may be mailed to Ms. Adina Wiley, Air Permits Section (6PD–R), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Ms. Adina Wiley, 214–665–2115, *wiley.adina@epa.gov.*

SUPPLEMENTARY INFORMATION: In the final rules section of this **Federal Register**, the EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action no further activity is contemplated. If the EPA receives relevant adverse comments, the direct final rule will be withdrawn and those public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

For additional information, see the direct final rule which is located in the rules section of this **Federal Register**.

Dated: March 16, 2015.

Samuel Coleman,

Acting Regional Administrator, Region 6.

[FR Doc. 2015–07123 Filed 3–27–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2015–0028; FRL–9925–47–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; West Virginia; Permits for Construction and Major Modification of Major Stationary Sources for the Prevention of Significant Deterioration

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing conditional approval for two State Implementation Plan (SIP) revisions submitted by the West Virginia Department of Environmental Protection (WVDEP) for the State of West Virginia on July 1, 2014 and June 6, 2012. These revisions pertain to West Virginia's Prevention of Significant Deterioration (PSD) permit program and include provisions for preconstruction permitting requirements for major sources of fine particulate matter ($PM_{2.5}$) found in West Virginia regulations. This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before April 29, 2015.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2015–0028 by one of the following methods:

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

B. *Email: campbell.dave@epa.gov.*

C. *Mail:* EPA–R03–OAR–2015–0028, David Campbell, Associate Director, Office of Permits and Air Toxics, Mailcode 3AP10, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2015–0028. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittals are available at the West Virginia Department of Environmental Protection, Division of Air Quality, 601 57th Street SE., Charleston, West Virginia 25304.

FOR FURTHER INFORMATION CONTACT: Mr. Paul Wentworth, (215) 814–2183, or by email at *Wentworth.paul@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The WVDEP submitted two SIP revisions to EPA on June 6, 2012 (the 2012 submittal) and on July 1, 2014 (the 2014 submittal). EPA is acting on these two submittals as a whole.[1] A summary of all the changes made in each of the submittals has been included in the docket for this action in a document titled, ''Summary of West Virginia PSD Changes.'' These SIP revision requests, if approved, would revise West Virginia's currently approved PSD program by amending Series 14 under Title 45 of West Virginia Code of State Rules (45CSR14).

On May 16, 2008, EPA promulgated a rule to implement the 1997 $PM_{2.5}$ National Ambient Air Quality Standard (NAAQS), including changes to the New Source Review (NSR) program (the 2008 NSR $PM_{2.5}$ Rule). *See* 73 FR 28321. The

[1] EPA is proposing to act on both SIP submittals in this notice because each submittal contains necessary procedural information related to West Virginia's revisions to its PSD regulations and development of its SIP submittals, which are required for SIP revisions by 40 CFR parts 51 and 52.

2008 NSR $PM_{2.5}$ Rule revised the NSR program requirements to establish the framework for implementing preconstruction permit review for the $PM_{2.5}$ NAAQS in both attainment and nonattainment areas.[2] The 2008 NSR $PM_{2.5}$ rule: (1) Required NSR permits to address directly emitted $PM_{2.5}$ and precursor pollutants; (2) established significant emission rates for direct $PM_{2.5}$ and precursor pollutants (including sulfur dioxide (SO_2) and oxides of nitrogen (NO_X)); (3) established $PM_{2.5}$ emission offsets; and (4) required states to account for gases that condense to form particles (condensables) in $PM_{2.5}$ emission limits.[3]

The 2008 NSR $PM_{2.5}$ Rule (as well as the more general $PM_{2.5}$ NAAQS implementation rule, the 2007 ''Final Clean Air Fine Particle Implementation Rule'' (2007 $PM_{2.5}$ Implementation Rule)[4]), was the subject of litigation before the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) in *Natural Resources Defense Council* v. *EPA* (hereafter, *NRDC* v. *EPA*).[5] On January 4, 2013, the D.C. Circuit remanded to EPA both the 2007 $PM_{2.5}$ Implementation Rule and the 2008 NSR $PM_{2.5}$ Rule. The court found that in both rules EPA erred in implementing the 1997 $PM_{2.5}$ NAAQS solely pursuant to the general implementation provisions of subpart 1 of part D of title I of the CAA (subpart 1), rather than pursuant to the additional implementation provisions specific to particulate matter in subpart 4 of part D of title I (subpart 4).[6] As a result, the D.C. Circuit remanded both rules and instructed EPA ''to re-promulgate these rules pursuant to subpart 4 consistent with this opinion.'' Although the D.C. Circuit declined to establish a deadline for EPA's response, EPA intends to respond promptly to the court's remand and to promulgate new generally applicable implementation regulations for the $PM_{2.5}$ NAAQS in accordance with the requirements of subpart 4. In the interim, however, states and EPA still need to proceed with implementation of the 1997 $PM_{2.5}$ NAAQS in a timely and effective fashion in order to meet statutory obligations under the CAA and to assure the protection of public health intended by those NAAQS. In a June 2, 2014 final rulemaking entitled ''Identification of Nonattainment Classification and Deadlines for Submission of State Implementation Plan (SIP) Provisions for the 1997 Fine Particle ($PM_{2.5}$) National Ambient Air Quality Standard (NAAQS) and 2006 $PM_{2.5}$ NAAQS; Final Rule,'' (79 FR 31566), EPA identified the classification status under subpart 4 for areas currently designated nonattainment for the 1997 and 2006 $PM_{2.5}$ NAAQS.[7]

As the requirements of Subpart 4 only pertain to nonattainment areas, EPA does not consider the portions of the 2008 NSR $PM_{2.5}$ Rule that address requirements for $PM_{2.5}$ attainment and unclassifiable areas to be affected by the *NRDC* v. *EPA* opinion. Moreover, EPA does not anticipate the need to revise any PSD permitting requirements promulgated in the 2008 NSR $PM_{2.5}$ Rule in order to comply with the D.C. Circuit's decision. This proposed rulemaking addresses West Virginia's PSD regulations. Thus, EPA has evaluated the regulations with applicable PSD requirements in the CAA, its implementing regulations, and the 2008 NSR $PM_{2.5}$ Rule.

The CAA's PSD provisions also establish maximum allowable increases over baseline concentrations—also known as ''increments''—for certain pollutants. EPA has the task of promulgating regulations to prevent the significant deterioration of air quality that would result from the emissions of pollutants EPA began regulating after Congress enacted the PSD provisions in the CAA, which includes $PM_{2.5}$. The PSD provisions establish preconstruction review and permitting of new or modified sources of air pollution. In 2007, EPA proposed a rule establishing increments for $PM_{2.5}$ and also proposed two screening tools that would exempt permit applicants from some air quality analysis and monitoring required for PSD: Significant impact levels (SILs) and significant monitoring concentration (SMC). *See* 72 FR 54112 (September 21, 2007). In our October 20, 2010 final rule (the $PM_{2.5}$ PSD Increments-SILs-SMC Rule), EPA set values for both SILs and SMC for $PM_{2.5}$. *See* 75 FR 64864.

The Sierra Club challenged EPA's authority to implement $PM_{2.5}$ SILs and SMC for PSD purposes as promulgated in the $PM_{2.5}$ PSD Increments-SILs-SMC Rule. *See Sierra Club* v. *EPA,* 705 F.3d 458 (D.C. Cir. 2013). On January 22, 2013, the D.C. Circuit granted a request from EPA to vacate and remand to the Agency the portions of the $PM_{2.5}$ PSD Increments-SILs-SMC Rule addressing the SILs for $PM_{2.5}$ (found in paragraph (k)(2) in 40 CFR 51.166 and 52.21), except for the parts codifying the $PM_{2.5}$ SILs at 40 CFR 51.165(b)(2), so that the EPA could voluntarily correct an error in the provisions. *Id.* at 463–66. The D.C. Circuit also vacated parts of the PSD Increments-SILs-SMC Rule establishing the $PM_{2.5}$ SMC, finding that the Agency had exceeded its statutory authority with respect to these provisions. *Id.* at 469.

In response to the D.C. Circuit's decision, EPA took final action on December 9, 2013 to remove the SIL provisions from the Federal PSD regulations in 40 CFR 52.21 and to revise the SMC for $PM_{2.5}$ to zero micrograms per cubic meter. *See* 78 FR 73698. Because the D.C. Circuit vacated the SMC provisions in 40 CFR 51.166(i)(5)(i)(*c*) and 52.21(i)(5)(i)(*c*), EPA revised the existing concentration for the $PM_{2.5}$ SMC listed in sections 51.166(i)(5)(i)(*c*) and 52.21(i)(5)(i)(*c*) to zero micrograms per cubic meter. EPA did not entirely remove $PM_{2.5}$ as a listed pollutant in the SMC provisions because to do so might lead to the issuance of permits that contradict the holding of the D.C. Circuit as to the statutory monitoring requirements. *Id.* (providing EPA's explanation for including the zero micrograms per cubic meter SMC).

On May 9, 2013, EPA had disapproved a narrow portion of a SIP revision submitted by the State of West Virginia on August 31, 2011 for revising West Virginia's PSD requirements in 45 CSR14 because the submittal did not satisfy the Federal requirement for inclusion of condensable emissions of PM (condensables) within the definition of ''regulated new source review (NSR) pollutant'' (at 45CSR14 section 2.66) for $PM_{2.5}$ and PM emissions less than or equal to ten micrometers in diameter (PM_{10}).[8]

[2] The PSD permitting program is the NSR permit program in areas attaining a particular NAAQS.

[3] On October 25, 2012, EPA took final action to amend the definition of ''*regulated NSR pollutant*'' promulgated in the 2008 NSR $PM_{2.5}$ Rule regarding the particulate matter (PM) condensable provision at 40 CFR 51.166(b)(49)(vi) and 52.21(b)(50)(i). *See* 77 FR 65107. The rulemaking removed the inadvertent requirement in the 2008 NSR $PM_{2.5}$ Rule that the measurement of condensable ''*particulate matter emissions*'' be included as part of the measurement and regulation of ''*particulate matter emissions.*''

[4] 72 FR 20586 (April 25, 2007).

[5] 706 F.3d 428 (D.C. Cir. 2013).

[6] The court's opinion did not specifically address the point that implementation under subpart 4 requirements would still require consideration of subpart 1 requirements, to the extent that subpart 4 did not override subpart 1. EPA assumes that the court presumed that EPA would address this issue of potential overlap between subpart 1 and subpart 4 requirements in subsequent actions.

[7] That June 2, 2014 rulemaking (79 FR 31566) also established a December 31, 2014 deadline for the submission of any additional attainment related SIP elements that may be needed to meet the applicable requirements of subpart 4.

[8] *See* 78 FR 27062 (May 9, 2013). The limited disapproval of the narrow portion of the August 31, 2011 SIP provision (concerning 45CSR14 section 2.66) is discussed in 78 FR 27062 and in 40 CFR 52.2522(j)(1) specifically.

II. Summary of SIP Revision and EPA Analysis

A. Summary of SIP Revision

Specifically, the revisions submitted by WVDEP on July 1, 2014 and June 6, 2012 involve amendments to 45CSR14 (Permits for Construction and Major Modification of Major Stationary Sources for the Prevention of Significant Deterioration) based on the Federal regulatory actions discussed above in section I. A summary of the changes made in the 2012 and 2014 submittals are available in the docket in a document titled, ''Summary of West Virginia NSR Changes.'' Generally, the revisions in the 2012 submittal were submitted to incorporate provisions related to the 2008 NSR $PM_{2.5}$ Rule. The 2014 submittal revises certain subdivisions of the 2012 submittal as shown in the table below:

Rule 45CSR14 subdivision	Description of change
2.66.a.1	Added PM condensable emissions to definition of ''regulated NSR pollutant''.
2.66.a.2	Added language identifying precursors to NAAQS pollutants to the definition of ''regulated NSR pollutant''.
16.7.c	Deleted 24-hour de minimis air quality impact concentration value for $PM_{2.5}$ (aka SMC for $PM_{2.5}$).
16.1.a & b	Added provision exempting requirements of 9.1 for stationary sources based on completeness date of permit applications.
9.2	Significant Impact Levels. Deleted this provision in its entirety.

In general, the 2014 submittal adds PM condensable emissions to the definition of ''regulated NSR pollutant'' and deletes SILs and SMC for $PM_{2.5}$ in the 45CSR14 provisions submitted for SIP approval.

B. EPA Analysis

EPA finds the revisions to 45CSR14 contained in the 2012 submittal and the 2014 submittal which were submitted by WVDEP for approval mirror the PSD requirements of the 2008 NSR $PM_{2.5}$ Rule with certain exceptions described in the next paragraph. The 2014 submittal addresses and corrects the deficiency identified in EPA's May 9, 2013 disapproval (78 FR 27062) by adding language to the provision at 45CSR14 section 2.66.a.1 which now includes PM condensable emissions in the definition of ''regulated NSR pollutant.'' Thus, EPA finds West Virginia has addressed the deficiency noted in our limited disapproval in 78 FR 27062.

However, while the 2014 submittal appropriately removes SILs for $PM_{2.5}$ consistent with the D.C. Circuit's *Sierra Club* v. *EPA* decision and our final December 9, 2013 rulemaking (78 FR 73698), West Virginia's PSD provision at 45CSR14–16.7.c (included in the 2014 submittal) does not include a SMC value of zero micrograms per cubic meter for $PM_{2.5}$ consistent with the D.C. Circuit's *Sierra Club* v. *EPA* decision and our December 9, 2013 rulemaking (78 FR 73698) which addressed the D.C. Circuit's vacature of the SMC provisions in 40 CFR parts 51 and 52 for $PM_{2.5}$. Therefore, West Virginia's PSD regulation, 45CSR14, does not fully meet the requirements for PSD programs as set forth in the 2008 NSR $PM_{2.5}$ Rule, the D.C. Circuit's decision on SILs and SMC in *Sierra Club* v. *EPA,* and in EPA's December 9, 2013 rulemaking addressing that decision for SILs and SMC.

However, on January 20, 2015, West Virginia committed to submitting an additional SIP revision with a revised PSD regulation at 45CSR14–16.7.c which will incorporate a SMC value of zero micrograms per cubic meter for $PM_{2.5}$ to address this discrepancy. West Virginia committed to submitting this SIP revision no later than one year following the effective date of the final rulemaking notice for conditional approval of the 2012 and the 2014 submittals so that EPA can conditionally approve the 2012 and 2014 submittals.[9] *See* CAA section 110(k)(4). With the exception of the absence of the SMC value of zero micrograms per cubic meter for $PM_{2.5}$ which WVDEP has committed to address, EPA finds the 2012 and 2014 submittals meet applicable requirements for a PSD permitting program in the CAA, its implementing regulations, and the 2008 NSR $PM_{2.5}$ Rule. The EPA is soliciting public comments on the issues discussed in this document. Any comments submitted in a timely manner will be considered before taking final action.

III. Proposed Action

EPA is proposing conditional approval of these West Virginia SIP revisions, the 2012 and 2014 submittals, because West Virginia is committing to submit an additional SIP revision addressing the deficiency identified by EPA regarding the deletion of the $PM_{2.5}$ SMC within one year of the date of EPA's final conditional approval and because the submittals otherwise meet CAA requirements as discussed in this proposed rulemaking. Once EPA has determined that West Virginia has satisfied this condition, the conditional approval of the 2012 and 2014 submittals will become a full approval. Should West Virginia fail to meet the condition specified above, the conditional approval of the 2012 and 2014 submittals will convert to a disapproval pursuant to CAA section 110(k)(4).

The full or partial disapproval of a SIP revision triggers the requirement under CAA section 110(c) that EPA promulgate a federal implementation plan (FIP) no later than two years from the date of the disapproval unless the State corrects the deficiency, and the Administrator approves the plan or plan revision before the Administrator promulgates such FIP. EPA has determined that West Virginia's 2014 submittal has rectified the deficiency regarding including condensables in the definition of regulated NSR pollutant noted in our limited disapproval in 78 FR 27062. Therefore, upon final approval of the 2014 submittal, the EPA is no longer required to promulgate a FIP to address the issue of PM condensables in the definition of regulated NSR pollutant for West Virginia's PSD permit program, and our narrow disapproval of the August 31, 2011 PSD SIP (for failure to include condensables in definition of regulated NSR pollutant) will become a full approval. However, EPA is proposing conditional approval for the 2012 and 2014 submittals due to West Virginia's lack of a $PM_{2.5}$ SMC with the value of zero micrograms per cubic meter.

IV. Incorporation by Reference

In this rule, 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 WV regulations at 45CSR14 regarding the Prevention of Significant

[9] West Virginia's letter from the Secretary of WVDEP committing to submit a revised provision in 45CSR14 to address the SMC for $PM_{2.5}$ is available in the docket for this rulemaking (EPA–R03–OAR–2015–0028) and available online at *www.regulations.gov.*

deterioration permitting requirements as discussed in section III of this preamble. The EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.com* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

V. Statutory and Executive Order Reviews

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

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

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

List of Subjects in 40 CFR Part 52

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

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

Dated: March 12, 2015.

William C. Early,

Acting Regional Administrator, Region III.

[FR Doc. 2015–07222 Filed 3–27–15; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 80, No. 60

Monday, March 30, 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–2014–0013]

Notice of Determination of the African Horse Sickness Status of Saudi Arabia

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that Saudi Arabia is free of African horse sickness (AHS). Based on our evaluation of the animal health status of Saudi Arabia, which we made available to the public for review and comment through a previous notice, the Administrator has determined that AHS is not present in Saudi Arabia and that the importation of horses, mules, zebras, and other equids from Saudi Arabia presents a low risk of introducing AHS into the United States.

DATES: Effective March 30, 2015.

FOR FURTHER INFORMATION CONTACT: Dr. Chip Wells, Senior Staff Veterinarian, Regionalization Evaluation Services, Sanitary Trade Issues Team, National Import Export Services, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 851–3300.

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 93 (referred to below as the regulations) prescribe the conditions for the importation into the United States of specified animals to prevent the introduction of various animal diseases, including African horse sickness (AHS). AHS is a fatal viral equine disease that is not known to exist in the United States.

Within part 93, § 93.308 contains requirements governing the importation of horses, mules, zebras, and other equids from regions where AHS exists in order to prevent the introduction of AHS into the United States. Equids from countries where AHS exists are eligible for importation into the United States only after undergoing a 60-day quarantine.

The regulations in 9 CFR part 92, § 92.2 (hereafter referred to as the ''regulations''), contain requirements for requesting the recognition of the animal health status of a region or for the approval of the export of a particular type of animal or animal product to the United States from a foreign region. If, after review and evaluation of the information submitted in support of the request the Animal and Plant Health Inspection Service (APHIS) believes the request can be safely granted, APHIS will make its evaluation available for public comment through a notice published in the **Federal Register**. Following the close of the comment period, APHIS will review all comments received and will make a final determination regarding the request that will be detailed in another notice published in the **Federal Register**.

On June 12, 2014, we published in the **Federal Register** (79 FR 33714–33715, Docket No. APHIS–2014–0013) a notice [1] in which we announced the availability for review and comment of our evaluation of the animal health status of Saudi Arabia relative to AHS. In that document, titled ''APHIS Evaluation of the African Horse Sickness (AHS) Status of the Kingdom of Saudi Arabia'' (November 2013), we presented the results of our evaluation of the risk of introducing AHS into the United States via the importation of equids from Saudi Arabia.

We solicited comments on the notice for 60 days ending on August 11, 2014. We received 11 comments by that date, from industry groups and State departments of agriculture. The comments we received are discussed below by topic.

Disease Status

The majority of commenters expressed concern regarding APHIS' recognition of Saudi Arabia as free of AHS because the World Organization of Animal Health (OIE) does not currently recognize Saudi Arabia as free of AHS. Two commenters asked whether Saudi Arabia has petitioned OIE to be recognized as free of AHS.

APHIS evaluations of animal disease status of countries are conducted independently of OIE evaluations in accordance with OIE standards for importing countries. Upon request by the Government of Saudi Arabia, APHIS conducted an import risk assessment using the guidelines established in the regulations. As a result of that assessment, APHIS concluded that Saudi Arabia is free of AHS.

OIE only recently (May 2014) began official recognition of the AHS status of regions in the world. Countries must formally request OIE recognition and submit a dossier of supporting information. APHIS' evaluation of Saudi Arabia was completed prior to May 2014 when OIE first published its list of regions recognized as AHS-free. APHIS has been informed by Saudi Arabian Ministry of Agriculture (MOA) officials that Saudi Arabia intends within the next few months to submit documentation to OIE requesting AHS-free recognition.

Several commenters expressed concern regarding the adequacy of the research leading to our conclusion that Saudi Arabia is free of AHS. Four commenters noted that the information used to support that conclusion was provided by Saudi Arabia.

APHIS evaluates the best available information in accordance with our regulations and with international standards set by the OIE under chapter 2.1 of their Terrestrial Animal Health Code. Often the best and only information available is supplied by the requesting country, although, whenever possible, APHIS considers third party information that is reliable and in accord with current scientific thinking. This practice is consistent with United States Government obligations under applicable international treaties governing trade.

One commenter was concerned that AHS has previously been present within Saudi Arabia.

The last case of AHS in Saudi Arabia was in 1989 and no further outbreaks have been reported since that time. The international standard for AHS-freedom set by OIE is 2 years without an outbreak. Saudi Arabia exceeds this time standard by more than 23 years. Furthermore, multiple surveillance studies since 1992 have not demonstrated the presence of AHS virus in the country. Saudi Arabian law

[1] To view the notice, the assessment, and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0013.*

requires mandatory notification of AHS virus throughout the country and AHS vaccination is prohibited. Based on these and other factors described in the risk assessment, APHIS has concluded that Saudi Arabia is free of AHS.

Surveillance and Control Measures

Many commenters stated that they had no confidence in Saudi Arabia's surveillance and control measures for AHS given its limited number of veterinarians and/or clinics in relation to the country's size or the size of its equid population. Two commenters expressed concern whether veterinarians in Saudi Arabia are qualified to diagnose cases of AHS.

APHIS evaluated the veterinary infrastructure of Saudi Arabia and concluded that it has a sufficient number of competent veterinarians to effectively manage its import/export surveillance and AHS disease control responsibilities. Saudi Arabia is roughly one fifth the size of the United States. However, most of the country is uninhabited desert. Therefore, its horse population is concentrated in several small areas, particularly the cities of Taif and Riyadh where most major equestrian events and races occur. In addition, the horse population of Saudi Arabia is estimated to be 16,500, which is relatively small in comparison to the estimated 9 million horses in the United States.

Saudi Arabia's MOA has an office within each of Saudi Arabia's 13 provinces, as well as over 190 branch offices and veterinary clinics in local communities throughout the kingdom. A total of 389 veterinarians and 210 veterinary assistants work under the MOA. These branch offices provide veterinary services for treatment of farm and pet animals in addition to official animal health control measures such as vaccination, sampling, and agriculture extension work. The Ministry also operates 39 mobile veterinary clinics out of the provincial or branch offices throughout the kingdom. There are also 80 private veterinary clinics in the kingdom.

There are two veterinary colleges in Saudi Arabia: King Faisal University in Al-Hofouf and King Saud University in Al Qassim. APHIS reviewed documentation of the AHS training program offered by the MOA to Saudi Arabian veterinarians in cooperation with these colleges and concluded that the content was comparable to training offered in the United States and is taught by well-qualified, internationally credentialed veterinary school faculty.

Several commenters expressed concern that the methodology behind AHS surveillance in Saudi Arabia was not explained in more detail and suggested that more surveillance be conducted. Two commenters stated that, although our evaluation cites the sampling of 750 horses and donkeys between 1997 and 2009, it fails to explain how animals were chosen for sampling or how the survey was conducted.

The MOA conducted six AHS surveillance surveys between 1997 and 2009. Surveys were conducted in 1997, 1999, 2001–2002, 2005, 2008, and 2009. APHIS evaluated the surveillance data and summarized their results in our evaluation. Several commenters incorrectly stated that 750 samples were collected during the period of 1997–2009. As mentioned in our evaluation of the animal health status of Saudi Arabia relative to AHS, a total of 750 animals (460 donkeys and 290 horses) in Saudi Arabia, out of an approximate population of 13,000, were sampled in 1997 alone. That number was chosen to provide 99 percent confidence of detecting AHS infection at a prevalence level of 1 percent. Samples were randomly selected with no more than five samples collected in any single stable or village and were collected in all regions of the country. However, a greater emphasis was placed on targeting samples, especially in donkeys, in the southwestern AHS control zone. Donkeys were targeted for increased sampling since that species would have an increased likelihood of subclinical infection and their population was higher in the AHS control zone. The AHS control zone is a region in the southwestern portion of Saudi Arabia bordering Yemen that acts as a buffer to separate the area where reintroduction of AHS would most likely occur. No equids from the control zone are allowed entry into the rest of Saudi Arabia and no equids from Yemen are allowed into Saudi Arabia. Test results indicated that no active AHS infection was present in the sampled animals.

Subsequent surveys collected additional samples in both nationwide and regionally targeted surveys. In 1999, the MOA conducted a smaller nationwide AHS statistical survey as a follow-up to the 1997 survey. In that survey, 250 samples were randomly collected from all regions of the country. The 2001–2002 survey collected 324 samples and targeted both animals in the AHS control zone and competition horses primarily stabled in the Riyadh area. The 2005 survey, which tested 79 samples, was conducted only in the southwest AHS control zone. The 2008 and 2009 surveys, both of which also focused on animals in the AHS control zone, collected 167 and 125 samples respectively. None of the surveys found evidence of viral activity. Animals that showed low level titers on the initial screening were retested after 30 and 60 days and titers were found to be either stable, decreased, or absent. Therefore, APHIS concluded that the surveys were statistically valid and sufficiently demonstrated AHS freedom.

In addition to these surveys, active surveillance data was collected from the pre-export testing of horses leaving Saudi Arabia. A total of 4,055 horses tested negative for AHS before being exported from Saudi Arabia between 1999 and 2011. All imported equids must test negative for AHS before being admitted into the country.

Two commenters expressed concern regarding Saudi Arabia's lack of a written emergency response plan to deal with a potential AHS outbreak. The commenters asked how, without a written emergency response plan, MOA can ensure that passive surveillance is done correctly and adheres to all MOA rules and regulations. The commenters further asked how MOA can maintain that Saudi Arabia is AHS free when horses could show clinical signs of AHS and be euthanized and buried without the MOA ever knowing about it.

As mentioned in the risk assessment, APHIS recommended to the MOA that Saudi Arabia would benefit by having a written AHS emergency response plan, along with periodic training and scenario exercises to simulate its implementation even though AHS virus has been absent in the country for a quarter century. APHIS believes that a written emergency plan would enhance Saudi Arabia's ability to quickly respond in the event of reintroduction of AHS. A quick response to detect, contain, and eradicate any AHS reintroduction would minimize disruption of trade. However, APHIS concludes that the lack of a written response plan does not preclude removal of Saudi Arabia from the list of regions APHIS considers affected with AHS. Reoccurrence of AHS in the country would result in suspension of equine trade. Resumption of trade would be dependent on subsequent control and eradication. APHIS believes that if the MOA has a written AHS emergency response plan then the length of time needed for this process would be minimized.

Compulsory notification of AHS suspicion and an effective veterinary infrastructure are necessary components of an AHS passive surveillance system. Saudi Arabian law requires notification of AHS suspicion. Based on

observations cited in our evaluation, APHIS concludes that the MOA is an effective central veterinary authority and provides veterinary services at the regional and local levels. Specifically, APHIS cites MOA's strategy of directly providing veterinary services though government operated veterinary clinics. The MOA employs a total of 389 veterinarians and 210 veterinary assistants and operates 39 mobile veterinary clinics. APHIS believes this practice encourages horse owners to call and report suspicious signs and symptoms of illness to ministry officials. In addition to the MOA veterinary clinics, there are 80 private veterinary clinics operating in Saudi Arabia. Similar to the United States, professional ethics and standards encourage compliance with the notification requirement for AHS suspicion.

While it is possible that AHS-infected horses could be euthanized and buried without being reported to the MOA, this possibility exists for any country in the world and APHIS believes it to be an unlikely scenario. Reintroduction of AHS into Saudi Arabia would likely result in multiple cases with high mortality, an event that would be difficult to keep hidden. Because vaccination has been illegal for over 11 years, Saudi Arabia now has a large number of AHS-susceptible equids. These animals functionally serve as sentinels for the disease. APHIS believes the number of unvaccinated equids is sufficiently high that AHS would be observed if it were present.

Border Controls

Many commenters expressed their belief that Saudi Arabia's borders are ''porous.'' The commenters expressed concerns that equids, including feral horses and donkeys, could enter Saudi Arabia from neighboring countries such as Oman and Yemen that are not free of AHS and subsequently enter the United States without being subject to the 60-day quarantine or potentially infect other equids that could enter the United States without being subject to the 60-day quarantine. Two commenters asked for evidence that MOA has conducted active surveillance of the country's feral population of non-horse equids to establish their freedom from evidence of AHS.

APHIS evaluated Saudi Arabia's border controls, including those along its southern border with Yemen and Oman where illegal entry of equids could pose a pathway for AHS introduction. APHIS recognizes the potential for illegal smuggling along many international borders where land crossing is possible. However, the extremely harsh desert along Saudi Arabia's border with Oman and much of Yemen provides a natural barrier that is considered to be sufficient to prevent the illegal entry of equids into Saudi Arabia. In addition, Saudi Arabia's southwest border with Yemen is very mountainous and contains a very limited number of potential routes for horses and donkeys to cross into Saudi Arabia. These mountain passes are regularly patrolled by Saudi Arabia's Al-Mujahedeen (border guards). APHIS considers the potential of being caught by these border patrols and the resultant consequences to be sufficient to deter the illegal smuggling of horses and donkeys into the southwestern region of Saudi Arabia. Furthermore, as stated previously, this southwest region is included in the AHS control zone from which movement of equids to the remainder of Saudi Arabia, as well as to any third country, is prohibited. Thus the AHS control zone provides a second layer of movement controls. Saudi Arabia lacks feral equid populations. Therefore, surveillance of these populations is not necessary or possible. In addition, as stated previously, all equids must test negative for AHS before being imported into Saudi Arabia. For these reasons, APHIS considers the illegal movement of horses from Oman and Yemen to the United States via Saudi Arabia extremely unlikely.

As mentioned in our evaluation, the MOA operates a border inspection post on King Fahad's causeway, which connects Saudi Arabia with Bahrain. That causeway is the only land crossing between the two countries. Two commenters expressed concern regarding oversight of the diplomatic lane on the causeway that is reserved for use by royal families and high government officials, citing the illegal movement of eight horses from Bahrain through this lane. The commenters asked how long the horses were in Saudi Arabia before it was determined they were imported illegally, how many other horses they came into contact with, and whether the incident led to greater oversight or a change in regulations regarding the diplomatic lane.

All horses, regardless of consignee, entering Saudi Arabia are required to have an import permit and are required to stop at the border inspection station for document review and inspection. At the time of the cited incident, Saudi Arabia prohibited the importation of equids from Bahrain due to an outbreak of glanders in that country. Despite these movement restrictions, individuals illegally moved eight horses into Saudi Arabia by taking advantage of diplomatic courtesies. However, secondary safeguards that regulate and control animal identification and internal movement resulted in prompt detection and seizure of these eight horses within 1 day, upon arrival at their intended destination in the Riyadh area. Lacking proper documentation of border inspection, these animals were promptly seized and quarantined before having contact with any other horses. MOA officials indicated that the Government of Saudi Arabia has been in discussions with the Government of Bahrain regarding the misuse of the diplomatic lanes. APHIS considers this quick response to be evidence of the efficacy of Saudi Arabia's animal movement controls and gives us confidence in Saudi Arabia's commitment and ability to enforce its import regulations.

Vectors

Many commenters expressed concern regarding the possibility of AHS being introduced into Saudi Arabia via wind-borne insect vectors from regions where AHS is present. Two commenters asked how APHIS can consider the desert along Saudi Arabia's southern border an effective natural barrier against the introduction of AHS when AHS vectors can cross the Bab el-Mandeb, a 20 mile wide strait separating Djibouti and Yemen.

APHIS acknowledges the presence of competent AHS vectors in Saudi Arabia. However despite their presence, surveillance over an extended period of time has not detected the presence of the AHS virus in the country. Although theoretically plausible, the introduction of AHS into Saudi Arabia from endemic areas of Africa via windblown virus-infected vectors has never been documented. The southwestern corner of Saudi Arabia is approximately 160 miles from Eritrea. Furthermore, the southwestern coastal region of Saudi Arabia is separated from the remainder of the country by a mountain range that is sufficiently high to be considered a natural barrier for spread of the insect vectors capable of transmitting the AHS virus. As described in our evaluation, this region is incorporated into Saudi Arabia's AHS control zone from which equine movement to the remainder of the country is prohibited and is an area of intensified AHS surveillance. APHIS considers surveillance conducted in this region reasonable to detect potential AHS reintroduction. The remainder of Saudi Arabia's southern border with Yemen and Oman is also protected by a natural barrier. The Rub al Khali, or

''Empty Quarter,'' is a vast uninhabited desert where conditions are inhospitable for life.

Historical incursions of AHS have been associated with the movement of infected horses. Because the focus of the evaluation was on Saudi Arabia, APHIS did not mention, but does consider, Bab el Mandeb to be a natural barrier for equid movements between Djibouti and Yemen. While APHIS considers Djibouti, as well as most of the African continent, to be AHS-affected, Djibouti has never reported outbreaks of AHS to the OIE. AHS is endemic in central and southern Africa and periodically spreads to northern Africa and countries around the Mediterranean. Saudi Arabia is separated from Africa by the Red Sea, which also serves as a natural barrier for equid movement. Equine movement restrictions and the natural barrier of the mountains and desert significantly reduce the risk of spreading AHS virus into other areas of the country.

Benefits and Impacts

Several commenters noted that only eight horses were imported into the United States from Saudi Arabia between 1999 and 2011. Given the low number of horse imports, the commenters questioned the benefit of increased trade with Saudi Arabia relative to the potential risk.

APHIS believes that the low number of imports reflects the trade barrier created by the current 60-day quarantine requirement. We assessed the risk and found no scientific basis justifying the continued listing of Saudi Arabia as a region affected by AHS. Therefore, in accordance with United States obligations under the OIE's Sanitary and Phytosanitary Agreement, APHIS is taking the action to remove Saudi Arabia from this list. As a result of this action, APHIS estimates the most likely effect will be an increase in the temporary movement of horses between Saudi Arabia and the United States for racing, competitions, and breeding. The current 60-day arrival quarantine required for horses entering the United States from Saudi Arabia is costly to horse owners (including U.S. owners) and creates hardships for maintaining the conditioning of competitive animals and care of breeding mares with foals. Horses currently move in and out of Saudi Arabia to the European Union and Arabian Gulf States for racing, competition, and breeding. Saudi horse owners have expressed the desire to compete in races and other equestrian competitions in the United States, as well as transport horses for breeding, but are inhibited by the cost and limitations of the current quarantine. APHIS cannot estimate with certainty the number of horse movements to and from Saudi Arabia that will result from this action. However, we believe the number to be relatively low.

Budget

Table 1 in our evaluation shows the total budget for MOA's Animal and Plant Quarantine Department from 2011 to 2014. Saudi Arabia's animal disease control activities, including for AHS, are reflected in that budget. Two commenters noted that the budget for the Animal and Plant Quarantine Department increased by $4,571,259 since 2011 and asked how APHIS can be certain that the increase went to fund AHS control and surveillance activities. The commenters also asked what Saudi Arabia's Animal and Plant Quarantine Department's budget was in 2009 and 2010.

The budget figures cited in Table 1 of the evaluation reflect the total budget for MOA's Animal and Plant Quarantine Department. Each of those three annual budgets includes a line item of $3,999,465 specifically earmarked as a contingency fund to respond to any foreign animal disease (FAD) emergency, including AHS. In addition, MOA officials have the option to request supplemental funding if emergency response costs exceed the appropriated contingency funds. The increase in the budgets over the 3 years reflects increases in the appropriations for veterinary personnel. Our evaluation reviewed the budgets for the 3 most current years and we believe that was sufficient to determine Saudi Arabia's ability to respond to an outbreak of AHS.

Impacts

Many commenters expressed concern regarding the potential impacts to the U.S. horse industry if AHS were to enter the United States, including job losses, high mortality, and the potential destruction of the horse industry. Several commenters questioned whether APHIS has the resources to deal with a potential AHS outbreak in the United States.

While APHIS agrees that the consequences of an AHS introduction into the United States could be severe, we do not believe that an outbreak would result in the catastrophic consequences the commenters describe. Such catastrophic consequences would be more likely associated with a highly contagious disease or one that spreads widely before detection. As stated in our evaluation, AHS is an infectious, but non-contagious, insect-transmitted, viral disease with high mortality in horses and mules. Recent history indicates that AHS outbreaks in other countries have not resulted in widespread infection, including the 1989 outbreak in Saudi Arabia which was limited to affecting three horses. Disease controls currently available, such as diagnostic capabilities, vector controls, and vaccination, likely contribute to limiting the spread of AHS outbreaks. APHIS believes that an introduction of AHS into the United States would be quickly detected, contained, and eradicated. In the evaluation, APHIS considered the consequences of an AHS introduction along with the exposure and release risks and concluded the overall risk of introducing AHS into the United States via the importation of horses from Saudi Arabia to be very low.

APHIS has resources and is prepared to respond to potential FAD outbreaks, including outbreaks of AHS. APHIS has established the Foreign Animal Disease Preparedness and Response Plan (FAD PReP) to provide a framework for FAD preparedness and response. This document provides the response strategies, zone and premises designations, and critical activities for controlling, containing, and eradicating an FAD. It is available on our Web site at: *http://www.aphis.usda.gov/animal_health/emergency_management/downloads/documents_manuals/fadprep_manual_2.pdf.* A companion document, the APHIS Foreign Animal Disease Framework: Roles and Coordination, provides an overview of FAD PReP, Federal roles, APHIS authorities and funding process, incident management, and communication strategy. This document is available at: *http://www.aphis.usda.gov/animal_health/emergency_management/downloads/documents_manuals/fadprep_manual_1.pdf.* Additional APHIS FAD emergency management documents may be found at: *http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalhealth?1dmy&urile=wcm%3apath%3a%2Faphis_content_library%2Fsa_our_focus%2Fsa_animal_health%2Fsa_emergency_management%2Fct_fadprep.*

Our evaluation cites the statistic that the mortality rate for horses infected with AHS is 70 to 95 percent. Two commenters asked how APHIS can be sure of these numbers.

The numbers cited come from the consensus of global scientific knowledge regarding the mortality rates described in our evaluation. Specifically, the mortality rate for horses infected with AHS was taken from the OIE Web site (*http://www.oie.int/fileadmin/Home/eng/Animal_*

Health_in_the_World/docs/pdf/Disease_cards/AFRICAN_HORSE_SICKNESS.pdf) and the Iowa State University: The Center for Food Security & Public Health Web site (*http://www.cfsph.iastate.edu/Factsheets/pdfs/african_horse_sickness.pdf*).

Compensation

Two commenters asked whether APHIS would be able to provide compensation for horses that may need to be euthanized for AHS.

APHIS has the authority to provide indemnity in the case of an FAD outbreak. In the event of an FAD outbreak such as AHS, APHIS may consider indemnity funding. Specific decisions regarding indemnity would depend on the situation and available funding sources.

Based on the evaluation and the reasons given in this document in response to comments, we are recognizing Saudi Arabia as free of AHS and removing it from the list of regions considered affected with AHS which is found on the APHIS Web site at *http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/importexport* and following the link to ''Animal or Animal Product.'' Copies of the list are also available via postal mail, fax, or email from the person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 24th day of March 2015.

Jere L. Dick,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015–07212 Filed 3–27–15; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2014–0008]

Notice of Decision To Authorize the Importation of Fresh Figs From Mexico Into the Continental United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our decision to authorize the importation of fresh figs from Mexico into the continental United States. Based on the findings of a pest risk analysis, which we made available to the public to review and comment through a previous notice, we have concluded that the application of one or more designated phytosanitary measures will be sufficient to mitigate the risks of introducing or disseminating plant pests or noxious weeds via the importation of fresh figs from Mexico.

DATES: Effective March 30, 2015.

FOR FURTHER INFORMATION CONTACT: Mr. George Apgar Balady, Senior Regulatory Policy Specialist, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1231; (301) 851–2240.

SUPPLEMENTARY INFORMATION: Under the regulations in ''Subpart—Fruits and Vegetables'' (7 CFR 319.56–1 through 319.56–71, referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) prohibits or restricts the importation of fruits and vegetables into the United States from certain parts of the world to prevent plant pests from being introduced into or disseminated within the United States.

Section 319.56–4 contains a performance-based process for approving the importation of commodities that, based on the findings of a pest risk analysis, can be safely imported subject to one or more of the designated phytosanitary measures listed in paragraph (b) of that section.

In accordance with that process, we published a notice [1] in the **Federal Register** on June 12, 2014 (79 FR 33716–33717, Docket No. APHIS–2014–0008), in which we announced the availability, for review and comment, of a pest list and risk management document (RMD) regarding the risks associated with the importation into the continental United States of fresh figs from Mexico.

We solicited comments on the pest list and RMD for 60 days, ending on August 11, 2014. We received three comments by that date, from an exporter, an organization of State plant regulatory agencies, and a State department of agriculture. The comments are discussed below.

The pest list identified six quarantine pests that are likely to follow the pathway of fresh figs imported from Mexico into the continental United States: *Anastrepha fraterculus, A. ludens, A. serpentina, Ceratitis capitata, Maconellicoccus hirsutus,* and *Nipaecoccus viridis.*

Two commenters acknowledged that the mitigation measures described in the RMD would likely be enough to mitigate the risks of all six quarantine pests, but requested that figs from Mexico not be distributed in Florida due to the risk of an accidental or incidental introduction of quarantine pests into the State.

As described in the RMD, we are requiring figs from Mexico to be treated with irradiation to neutralize all plant pests of the class Insecta. Section 305.9 specifies the requirements for the irradiation of imported commodities. These requirements provide effective safeguards for articles irradiated either prior to or after arrival in the United States. In addition, each consignment is subject to inspection at the U.S. ports of entry and must be found free of all quarantine pests. We are confident that these requirements will adequately mitigate the risks associated with the importation of fresh figs from Mexico.

One commenter asked what phytosanitary measures would apply to figs exported from fruit fly-free areas of Mexico and whether those treatments will negate the figs' organic status.

Under § 319.56–5, certain fruits and vegetables may be imported into the United States provided that the fruits or vegetables originate from an area that is free of a specific pest or pests. As such, figs produced in fruit fly-free areas of Mexico would be eligible for importation into the United States without treatment for fruit flies. However, the figs would be subject to the labeling, certification, and safeguarding requirements of § 319.56–5(e), the general requirements in § 319.56–3, and would have to be inspected and found free of *M. hirsutus* and *N. viridis.*

Therefore, in accordance with § 319.56–4(c)(2)(ii), we are announcing our decision to authorize the importation of fresh figs from Mexico into the continental United States subject to the following phytosanitary measures:

- The figs may be imported into the continental United States in commercial consignments only.
- The figs must be irradiated in accordance with 7 CFR part 305 with a minimum absorbed dose of 150 Gy.
- If irradiation treatment is applied outside the United States, each consignment of fruit must be jointly inspected by APHIS and the national plant protection organization (NPPO) of Mexico and accompanied by a phytosanitary certificate (PC) attesting that the fruit received the required irradiation treatment. The PC must also include an additional declaration stating that the consignment was inspected and found free of *M. hirsutus* and *N. viridis.*
- If irradiation treatment is applied upon arrival in the United States, each consignment of fruit must be inspected by the NPPO of Mexico prior to

[1] To view the notice, pest list, RMD, and comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0008.*

departure and accompanied by a PC attesting that the fruit was inspected and found free of *M. hirsutus* and *N. viridis.*

• The commodity is subject to inspection at the U.S. port of entry.

These conditions will be listed in the Fruits and Vegetables Import Requirements database (available at *http://www.aphis.usda.gov/favir*). In addition to these specific measures, figs from Mexico will be subject to the general requirements listed in § 319.56–3 that are applicable to the importation of all fruits and vegetables.

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.

Done in Washington, DC, this 25th day of March 2015.

Michael C. Gregoire,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015–07231 Filed 3–27–15; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2013–0047]

U.S. Department of Agriculture Stakeholder Workshop on Coexistence

ACTION: Notice; extension of comment period.

SUMMARY: We are extending the comment period for issues and proposals discussed during the workshop on agricultural coexistence that was held on March 12–13, 2015. This action will allow interested persons additional time to prepare and submit comments.

DATES: The comment period for the notice published on February 3, 2015 (80 FR 5729) is extended. We will consider all comments that we receive on or before April 10, 2015.

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

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docket Detail;D=APHIS-2013-0047.*

• *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2013–0047, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Any comments we receive may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0047* 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: Mr. Michael Tadle, Program Analyst, Planning, Evaluation, and Decision Support, PPD, APHIS, 4700 River Road, Unit 120, Riverdale, MD 20737; (301) 851–3140; *Michael.A.Tadle@aphis.usda.gov.*

SUPPLEMENTARY INFORMATION: On February 3, 2015, we published in the **Federal Register** (80 FR 5729–5731, Docket No. APHIS–2013–0047) a notice [1] to announce that the U.S. Department of Agriculture was holding a workshop on agricultural coexistence, the objective of which was to advance an understanding of agricultural coexistence and discuss how to make coexistence achievable for all stakeholders. The 2-day workshop, which was held on March 12–13, 2015, also provided an opportunity to learn from stakeholders representing a wide range of interests with respect to agricultural coexistence.

In that notice, we stated that comments on issues and proposals discussed during the workshop would be accepted from March 13, 2015, through March 27, 2015. We are extending the comment period on Docket No. APHIS–2013–0047 for an additional 14 days to April 10, 2015. This action will allow interested persons additional time to prepare and submit comments.

Done in Washington, DC, this 25th day of March 2015.

Michael C. Gregoire,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015–07210 Filed 3–27–15; 8:45 a.m.]

BILLING CODE 3410–34–P

[1] To view the workshop notice and comments, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0047.*

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2015–0018]

Notice of Request for Extension of Approval of an Information Collection; Importation of Small Lots of Seed

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection associated with the regulations for the importation of small lots of seed into the United States.

DATES: We will consider all comments that we receive on or before May 29, 2015.

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

• Federal eRulemaking Portal: Go to *http://www.regulations.gov/#!docket Detail;D=APHIS-2015-0018.*

• Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS–2015–0018, 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-2015-0018* 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: For information on the regulations for the importation of small lots of seed into the United States, contact Ms. Lydia Colón, Regulatory Policy Specialist, PPP, RPM, PHP, PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737; (301) 851–2302. For copies of more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

SUPPLEMENTARY INFORMATION:

Title: Importation of Small Lots of Seed.

OMB Control Number: 0579–0285.

Type of Request: Extension of approval of an information collection.

Abstract: The Plant Protection Act (7 U.S.C. 7701 *et seq.*) authorizes the Secretary of Agriculture to restrict the importation, entry, or interstate movement of plants, plant products, and other articles to prevent the introduction of plant pests into the United States or their dissemination within the United States. The regulations contained in ''Subpart—

Plants for Planting'' (7 CFR 319.37–1 through 319.37–14) prohibit or restrict, among other things, the importation of living plants, plant parts, and seed for propagation.

These regulations allow small lots of seed to be imported into the United States under an import permit with specific conditions, including seed packet labeling, as an alternative to a phytosanitary certificate requirement.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

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

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

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

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.0356 hours per response.

Respondents: Importers, horticultural societies, arboreta, and small businesses.

Estimated annual number of respondents: 400.

Estimated annual number of responses per respondent: 26.

Estimated annual number of responses: 10,400.

Estimated total annual burden on respondents: 370 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.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 24th day of March 2015.

Jere L. Dick,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015–07224 Filed 3–27–15; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2011–0077]

Notice of Decision To Authorize the Importation of Fresh Tejocote Fruit From Mexico Into the Continental United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our decision to authorize the importation into the continental United States of fresh tejocote fruit from Mexico. Based on the findings of a pest risk analysis, which we made available to the public for review and comment through a previous notice, we have determined that the application of one or more designated phytosanitary measures will be sufficient to mitigate the risks of introducing or disseminating plant pests or noxious weeds via the importation of fresh tejocote fruit from Mexico.

DATES: Effective March 30, 2015.

FOR FURTHER INFORMATION CONTACT: Mr. David B. Lamb, Senior Regulatory Policy Specialist, PHP, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737; (301) 851–2103.

SUPPLEMENTARY INFORMATION: Under the regulations in ''Subpart—Fruits and Vegetables'' (7 CFR 319.56–1 through 319.56–71, referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture prohibits or restricts the importation of fruits and vegetables into the United States from certain parts of the world to prevent plant pests from being introduced into and spread within the United States.

Section 319.56–4 of the regulations contains a performance-based process for approving the importation of commodities that, based on the findings of a pest risk analysis (PRA), can be safely imported subject to one or more of the designated phytosanitary measures listed in paragraph (b) of that section. Under that process, APHIS publishes a notice in the **Federal Register** announcing the availability of the PRA that evaluates the risks associated with the importation of a particular fruit or vegetable. Following the close of the 60-day comment period, APHIS may begin issuing permits for importation of the fruit or vegetable subject to the identified designated measures if: (1) No comments were received on the PRA; (2) the comments on the PRA revealed that no changes to the PRA were necessary; or (3) changes to the PRA were made in response to public comments, but the changes did not affect the overall conclusions of the analysis and the Administrator's determination of risk.

In accordance with that process, we published a notice [1] in the **Federal Register** on September 29, 2011 (76 FR 60449–60450, Docket No. APHIS–2011–0077), in which we announced the availability, for review and comment, of a PRA that evaluated the risks associated with the importation into the continental United States of fresh tejocote fruit (*Crataegus pubescens*) from Mexico. The PRA consisted of a risk assessment identifying pests of quarantine significance that could follow the pathway of importation of fresh tejocote fruit from Mexico into the continental United States and a risk management document identifying phytosanitary measures to be applied to that commodity to mitigate the pest risk. We solicited comments on the notice for 60 days ending on November 28, 2011. We received five comments by that date. They were from a State agricultural official, a foreign national plant protection organization (NPPO), two domestic tejocote growers, and a domestic fruit and vegetable distributor. Four of these commenters opposed the importation of fresh tejocote fruit from Mexico into the United States.

Two commenters expressed a general concern about the phytosanitary risk of importing tejocote fruit from Mexico but did not mention a specific pest.

The PRA did not identify any pests of quarantine significance as following the pathway of commercial shipments of tejocote from Mexico into the United States. We concluded that the required phytosanitary measures listed in the PRA will result in the effective removal of any potential quarantine pests associated with the importation of tejocote from Mexico.

Another commenter opposed the importation of fresh tejocote fruit from Mexico on grounds that it has been demonstrated to be a host for

[1] To view the notice, the PRA, and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0077.*

Mediterranean fruit fly (*Ceratitis capitata*), or Medfly. The commenter stated that the Mexican State of Chiapas has had recurring outbreaks of Medfly and requested that imports of fresh tejocote fruit from Mexico not be permitted into the commenter's State until the shipping protocol described in the PRA has had sufficient time to demonstrate that Medfly outbreaks in Chiapas do not result in an introduction of Medfly into the United States. Another commenter opposed to the importation of tejocote fruit cited Web sites and unspecified articles and stated that they contain information about tejocote crop damage caused by fruit flies in parts of Mexico, including Chiapas, where tejocote is grown commercially.

We were unable to find information about tejocote crop damage in Mexico on the Web sites listed by the commenter. APHIS recognizes Mexico as having eradicated Medfly, a determination that has been corroborated by CABI, an internationally recognized pest monitoring resource.[2] While there have been occasional introductions of Medfly along the border between the Mexican State of Chiapas and Guatemala, APHIS has determined that no established populations of Medfly exist in any part of Mexico. Furthermore, APHIS operates the Moscamed program in cooperation with Guatemala and Mexico to detect and eradicate introductions into Mexico through surveillance trapping, fruit sampling, biological and mechanical controls, release of sterile Medflies, public education efforts, and the establishment of fruit fly-free areas. We have determined that the Moscamed program possesses the capability to detect, contain, and eradicate Medfly outbreaks within commercial tejocote growing areas of Mexico. If an outbreak of Medfly were to occur and APHIS determined that it posed an unacceptable phytosanitary risk to the United States, we would immediately prohibit the importation of fresh tejocote fruit from Mexico. This practice is consistent with actions we have taken toward imports of commodities from other countries considered free of certain quarantine pests when such pests appear in those countries and pose an unacceptable import risk to the United States.

The PRA identified three designated measures as necessary to ensure the safe importation of tejocote fruit from Mexico:

- The tejocote fruit must be imported in commercial consignments only.
- Each consignment of tejocote fruit must be accompanied by a phytosanitary certificate issued by the NPPO of Mexico stating the following: ''Tejocote fruit in this consignment were inspected and are free of pests.''
- Each shipment of tejocote fruit is subject to inspection upon arrival at port of entry to the United States.

One commenter noted that the PRA identified no quarantine pests likely to follow the pathway of commercial consignments. As a result, the commenter suggested that port-of-entry inspection be the only required measure.

APHIS has concluded that the measures indicated in the PRA are necessary to effectively mitigate the pest risk associated with fresh tejocote fruit imported from Mexico.

Only commercial consignments of tejocote fruit will be allowed to be imported from Mexico for sale and distribution. Commercial consignments, as defined in § 319.56–2, are consignments that an inspector identifies as having been imported for sale and distribution. Produce grown commercially is less likely to be infested with plant pests than noncommercial consignments. Noncommercial consignments are more prone to infestations because the commodity is often ripe to overripe, could be of a variety with unknown susceptibility to pests, and is often grown with little or no pest control.

Consignments of fresh tejocote fruit from Mexico will also be required to be accompanied by a phytosanitary certificate. The phytosanitary certificate provides additional assurance that the NPPO of Mexico has inspected the commodity and determined that it meets the requirements for importation into the United States and is free of pests.

Three commenters opposed the importation of tejocote fruit from Mexico on grounds that U.S. growers could suffer economically as a result of competition with imported tejocote fruit.

Under the Plant Protection Act (7 U.S.C. 7701 *et seq.*), we have the authority to prohibit or restrict the importation of plants and plant products only when necessary to prevent the introduction into or dissemination of plant pests or noxious weeds within the United States. We do not have the authority to restrict imports solely on the grounds of potential economic effects on domestic entities that could result from increased imports.

Therefore, in accordance with the regulations in § 319.56–4(c)(2)(ii), we are announcing our decision to authorize the importation into the continental United States of fresh tejocote fruit from Mexico subject to the following phytosanitary measures:

- The tejocote fruit must be imported in commercial consignments only.
- Each consignment of tejocote fruit must be accompanied by a phytosanitary certificate issued by the NPPO of Mexico stating the following: ''Tejocote fruit in this consignment were inspected and are free of pests.''
- Each shipment of tejocote fruit is subject to inspection upon arrival at port of entry to the United States.

These conditions will be listed in the Fruits and Vegetables Import Requirements database (available at *http://www.aphis.usda.gov/favir*). In addition to these specific measures, fresh tejocote fruit from Mexico will be subject to the general requirements listed in § 319.56–3 that are applicable to the importation of all fruits and vegetables.

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.

Done in Washington, DC, this 25th day of March 2015.

Michael C. Gregoire,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015–07234 Filed 3–27–15; 8:45 am]

BILLING CODE 3410–34–P

[2] CABI Invasive Species Compendium 2015: *http://www.cabi.org/isc/datasheet/12367.*

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

March 24, 2015.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the 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 should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@omb.eop.gov* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if they are received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food and Nutrition Service

Title: The Integrity Program (TIP) Data Collection.

OMB Control Number: 0584–0401.

Summary of Collection: This is a request for extension, without revision, to an existing collection. The Women, Infant, and Children (WIC) Program regulations at 7 CFR 246.12(j)(5), requires State agencies to report annually on their vendor monitoring efforts. The data collected is used by States agencies as a management tool and at the national level to provide Congress, senior FNS officials, as well as the general public, assurances that every reasonable effort is being made to ensure integrity in the WIC Program.

Need and Use of the Information: The Food and Nutrition Service (FNS) will collect information using forms FNS 698, Profile of Integrity Practices and Procedures; FNS 699, the Integrity Profile Report Form; and FNS 700, TIP Data Entry Form. The collected information from the forms will be analyzed and a report is prepared by FNS annually that (1) assesses State agency progress in eliminating abusive vendors, (2) assesses the level of activity that is being directed to ensure program integrity, and (3) analyzes trends over a 5-year period. The information is used at the national level in formulating program policy and regulations. At the FNS regional office level, the data is reviewed to identify possible vendor management deficiencies so that technical assistance can be provided to States, as needed. Without the information, FNS would not have timely and accurate data needed to identify and correct State agency vendor management and monitoring deficiencies and to implement corrective actions.

Description of Respondents: State, Local or Tribal Government.

Number of Respondents: 90.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 38.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2015–07120 Filed 3–27–15; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Meeting Notice of the National Agricultural Research, Extension, Education, and Economics Advisory Board

AGENCY: Research, Education, and Economics, USDA.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, 5 U.S.C. App 2, Section 1408 of the *National Agricultural Research, Extension, and Teaching Policy Act of 1977* (7 U.S.C. 3123), and the *Agricultural Act of 2014,* the United States Department of Agriculture (USDA) announces an open virtual meeting of the National Agricultural Research, Extension, Education, and Economics Advisory Board.

DATES: The National Agricultural Research, Extension, Education, and Economics Advisory Board will meet via teleconference on April 14, 2015, at 2:00 p.m. Eastern Daylight Time.

ADDRESSES: The meeting will take place virtually at the AT&T Meeting Room below. Please follow the pre-registration instructions to ensure your participation in the meeting.

Call-In instructions for Tuesday, April 14, 2015 at 2:00 p.m. Eastern Daylight Time:

Web Preregistration: Participants may preregister for this teleconference at *http://emsp.intellor.com?p=419202&do=register&t=8.* Once the participant registers, a confirmation page will display dial-in numbers and a unique PIN, and the participant will also receive an email confirmation of this information.

FOR FURTHER INFORMATION CONTACT: Michele Esch, Designated Federal Officer and Executive Director, National Agricultural Research, Extension, Education, and Economics Advisory Board, U.S. Department of Agriculture, 1400 Independence Avenue SW., STOP 0321, Washington, DC 20250–0321; telephone: (202) 720–3684; fax: (202) 720–6199; or email: *nareee@ars.usda.gov.*

SUPPLEMENTARY INFORMATION: On Tuesday, April 14, 2015, at 2:00 p.m. Eastern Daylight Time a virtual meeting of the National Agricultural Research, Extension, Education, and Economics Advisory Board will be conducted to hear the summary of findings and recommendations on the review of the animal handling, care, and welfare at the U.S. Meat Animal Research Center, hear stakeholder input received from this meeting as well as other written comments, and provide input on the report. The report is available at *www.ree.usda.gov.* This meeting is open to the public and any interested individuals wishing to attend. Opportunity for verbal public comment will be offered on the day of the meeting. Written comments by attendees or other interested stakeholders will be welcomed for the public record before and up to the day of the meeting (by close of business Tuesday, April 14, 2015). All written statements must be sent to Michele Esch, Designated Federal Officer and Executive Director, National Agricultural Research, Extension, Education, and Economics Advisory Board, U.S. Department of Agriculture, 1400 Independence Avenue SW., STOP 0321, Washington, DC 20250–0321; or email: *nareee@ars.usda.gov.* All statements will become a part of the official record of the National Agricultural Research, Extension, Education, and Economics Advisory Board and will be kept on file for public review in the Research, Education, and Economics Advisory Board Office.

Done at Washington, DC, this 20th day of March 2015.

Ann Bartuska,

Deputy Under Secretary, Research, Education, and Economics.

[FR Doc. 2015–07145 Filed 3–27–15; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

March 24, 2015.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995,

Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by April 29, 2015 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW., Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Animal Plant and Health Inspection Service

Title: Interstate Movement of Sheep and Goats; Recordkeeping for Approved Livestock Marketing Facilities and Slaughtering and Rendering Establishments.

OMB Control Number: 0579–0258.

Summary of Collection: The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. Disease surveillance and prevention is the most effective method for maintaining a healthy animal population and enhancing the ability of the Animal and Plant Health Inspection Service (APHIS) to help U.S. producers compete in the world market of animal and animal product trade. The Veterinary Services (VS) program of APHIS is the unit responsible for carrying out the disease prevention mission. One of the APHIS disease eradication programs addresses scrapie. Scrapie is a progressive, degenerative, and eventually fatal disease affecting the central nervous system of sheep and goats. APHIS' regulations 9 CFR 71.20 and 9 CFR 71.21 regarding the movement of livestock to require approved livestock auction market facilities, slaughtering establishments, and rendering establishments to maintain certain records for 5 years (2 years if the records regard only swine or poultry).

APHIS is merging the information collection 0579–0342, Recordkeeping for Approved Livestock Facilities, Slaughtering, and Rendering Establishments, into this package 0579–0258. These collections include the same regulations; therefore, it will be more efficient to have them consolidated into one collection. Collection 0579–0342 will be discontinued once this collection is approved.

Need and Use of the Information: In order for APHIS' Disease prevention program to be effective, its animal identification, recordkeeping, and other requirements must be carried out at livestock facilities that handle livestock and poultry moving in interstate commerce. The individual legally responsible for the day-to-day operation of the facility must execute an Approval of Livestock Facilities Agreement with APHIS. The information restricts the interstate movement of livestock within the United States to control diseases of concern and approve livestock facilities and slaughtering and rendering establishments that handle livestock moving in interstate commerce.

Description of Respondents: Business or other for-profit; State, Local or Tribal Government.

Number of Respondents: 234.

Frequency of Responses: Recordkeeping; Reporting: On occasion.

Total Burden Hours: 604.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2015–07119 Filed 3–27–15; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Mid-Atlantic Fishery Management Council (MAFMC); Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) will hold public meetings of the Council and its Committees.

DATES: The meetings will be held Tuesday, April 14, 2015 through Thursday, April 16, 2015. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held at: Ocean Place Resort, One Ocean Blvd., Long Branch, NJ 07740, telephone: (732) 571–4000.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State St., 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. The Council's Web site, *www.mafmc.org* also has details on the meeting location, proposed agenda, webinar listen-in access, and briefing materials.

SUPPLEMENTARY INFORMATION: The following items are on the agenda, though agenda items may be addressed out of order (changes will be noted on the Council's Web site when possible.)

Tuesday, April 14, 2015

12:30 p.m.–2 p.m.

Executive Committee (Closed Session)

—Review and approve Advisory Panel recommendations

2 p.m.

Council Convenes

2 p.m.–5:00 p.m.

Ecosystem Approach to Fisheries Management

—Discuss management approaches which address climate change and variability

—Discuss regulatory alternatives to address unmanaged forage fish

Wednesday, April 15, 2015

9 a.m.

Council Convenes

9 a.m.–10:30 a.m.

Golden Tilefish
—Review 2016 specifications
—Discuss timetable for Framework

10:30 a.m.–11:30 a.m.

2015 Implementation Plan
—Consider initiation of Deepwater Complex FMP
—Review and approve possible revisions to the Plan

11:30 a.m.–12 p.m.

Control Rule Clarifications
—Review staff and SSC recommendations
—Approve changes in regulatory language

1:30 p.m.–2 p.m.

Industry Funded Observer Amendment
—Discuss and approve additional alternatives for Public Hearing Document

2 p.m.–2:30 p.m.

River Herring Technical Expert Working Group (TEWG)
—Update on recent activities

2:30 p.m.–3 p.m.

Delaware River Herring/Shad Recreational Fishery, *John Punola*

3 p.m.–4 p.m.

Bycatch Reduction in Summer Flounder Recreational Fishery, *Dr. Jim Salierno and Carl Benson*

4 p.m.–5 p.m.

Proposed Rule—National Standards 1, 3, and 7, *Deb Lambert*

5 p.m.–6 p.m.

Listening Session—Squid Capacity Amendment Scoping, *Jason Didden*

Thursday, April 16, 2015

9 a.m.

Council Convenes

9 a.m.–1 p.m.

Business Session
Organization Reports
—NMFS Greater Atlantic Regional Office
—NMFS Northeast Fisheries Science Center
—NOAA Office of General Counsel
—NOAA Office of Law Enforcement
—U.S. Coast Guard
—Atlantic States Marine Fisheries Commission
Liaison Reports
—New England Council
—South Atlantic Council
Executive Director's Report, *Chris Moore*
—Review and approve changes to Council SOPPs
Science Report, *Rich Seagraves*
Committee Reports
—SSC
Continuing and New Business

Although non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during these meetings. Actions will be restricted to those issues specifically identified 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 the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are 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: March 25, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–07157 Filed 3–27–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD849

Fisheries of the South Atlantic; South Atlantic Fishery Management Council; Public Meeting

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

ACTION: Notice of a joint meeting of the South Atlantic Fishery Management Council's (Council) Shrimp Advisory Panel and Deepwater Shrimp Advisory Panel (AP).

SUMMARY: The South Atlantic Fishery Management Council will hold a joint meeting of its Shrimp and Deepwater Shrimp APs in North Charleston, SC. The meeting is open to the public.

DATES: The meeting will be held from 9 a.m. until 3 p.m. on Thursday, April 16, 2015.

ADDRESSES:

Meeting address: The meeting will be held at the Hilton Garden Inn, 5265 International Blvd., N. Charleston, SC 29418; telephone: (843) 308–9330.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC, 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC, 29405; telephone: (843) 571–4366 or toll free (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: The Shrimp and Deepwater Shrimp Advisory Panels will meet jointly and receive an update on the NOAA Fisheries Biological Opinion for shrimp that includes the status of terms and conditions for the fishery, the Southeast Data, Assessment, and Review (SEDAR) 2014 Shrimp Procedural Workshop including data and procedures for a shrimp stock assessment and bycatch estimations, and the Oculina Evaluation Team Report which includes a response by the team to consider a shrimp access area within the area currently closed to fishing. The AP members will provide comments and recommendations on these agenda items as appropriate. The AP members will also receive an update on the status of Amendment 8 to the Coral Fishery Management Plan to expand coral protected areas and address other business as necessary.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the council office (see **ADDRESSES**) 3 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Dated: March 26, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–07310 Filed 3–27–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Final Updated Framework for the National System of Marine Protected Areas and Response to Comments

AGENCY: National Marine Protected Areas Center, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric

Administration, Department of Commerce.

ACTION: Notice of availability of the final updated Framework for the National System of Marine Protected Areas of the United States and response to comments on Draft Updated Framework.

SUMMARY: The Department of Commerce and the Department of the Interior (DOI) jointly propose an updated Framework for the National System of Marine Protected Areas of the United States (Framework). The Framework is required by Executive Order 13158 on Marine Protected Areas (MPAs). This Framework provides overarching guidance for collaborative efforts among federal, state, commonwealth, territorial, tribal and local governments and stakeholders to implement an effective National System of MPAs (National System) from existing sites, build management capacity among MPA programs, coordinate collaborative efforts to address common management issues and identify ecosystem-based gaps in the protection of significant natural and cultural resources for possible future action by the nation's MPA authorities. This document updates the previous version of the Framework, completed in November 2008, using experience gained implementing the National System and advice from the Marine Protected Areas Federal Advisory Committee and MPA programs.

FOR FURTHER INFORMATION CONTACT: Lauren Wenzel, Acting Director, National Marine Protected Areas Center, 301–713–7265 or *lauren.wenzel@noaa.gov*.

Copies of the updated Framework can be downloaded or viewed on the Internet at *marineprotectedareas.noaa.gov*. Copies can also be obtained through the contact person noted above.

SUPPLEMENTARY INFORMATION:

I. Background on MPA Framework

The National Oceanic and Atmospheric Administration's (NOAA) National Marine Protected Areas Center (MPA Center), within the Office of National Marine Sanctuaries, in cooperation with the Department of the Interior (DOl), completed the *Framework for the National System of Marine Protected Areas of the United States* (Framework) to meet requirements under Executive Order 13158 on Marine Protected Areas (Order) in November 2008. NOAA and DOI updated this Framework to reflect five years of implementation experience as well as advice from MPA management agencies and the Marine Protected Areas Federal Advisory Committee. The purpose of this notice is to notify the public of the availability of the updated Framework and to respond to public comment received on a draft update published October 27, 2014.

Executive Order 13158 calls for the development of a National System of MPAs to ''enhance the conservation of our Nation's natural and cultural marine heritage and the ecologically and economically sustainable use of the marine environment for future generations.'' Established in November 2008, the National System provides a mechanism for MPA managers to voluntarily collaborate on shared management challenges; strengthen linkages among sites to enhance the management of marine resources; and build management capacity.

This proposed updated Framework is streamlined for greater clarity and readability, has an increased focus on the functions of the National System, and describes the role of the MPA Center in coordinating and supporting the National System. It also includes substantial revisions to the criteria for cultural resources, adding a criterion that allows MPAs created by tribes and indigenous people to be eligible for the National System.

II. Comments and Responses

On October 27, 2014, NOAA and DOI (agencies) published the updated Framework for public comment (79 FR 63899). By the end of the two-month comment period, five individual submissions had been received. Several of the comments raised more than one issue, so related comments have been summarized and grouped below into thematic categories. For each of the categories listed below, a summary of comments is provided, and a corresponding response provides an explanation and rationale about changes that were or were not made in the final updated Framework.

MPA Networks and New MPAs

Comment: The updated Framework puts a greater emphasis on expanding MPA networks and creating new MPAs, moving the focus from more pressing needs of existing sites. Moreover, the focus on ecosystem connectivity may not be appropriate for existing MPAs, and may not serve a larger conservation purpose.

Response: The development of MPA networks is a widely recognized marine conservation tool, acknowledged to be effective in providing the spatial links needed to maintain ecosystem processes and connectivity, as well as improving resilience of ecosystems and the communities that depend on them. NOAA and DOI believe that encouraging the science-based creation of MPA networks is fundamental to fulfilling the goals of the National System of MPAs. This focus on enhancing ecosystem connectivity will actually help realize the achievement of existing conservation objectives of MPAs.

The updated Framework notes the importance of fostering effective management of existing MPAs as well as identifying priorities for conservation where new MPAs may be an appropriate solution. Contributing to planning for new MPAs is not a major focus of the updated Framework, but part of an overall approach to developing an effective and representative National System of MPAs.

Defining and Implementing ''Avoid Harm'' Provision

Comment: The updated Framework should provide more clarity regarding definitions and implementation of the requirement in Executive Order 13158 for federal agencies to ''avoid harm'' to the resources protected by an MPA.

Response: The updated Framework notes that the Executive Order does not provide new legal authority for any federal agency or the MPA Center to review activities of any other federal agency or to create different standards for existing reviews. Instead, the implementation of Section 5, and the national policy it articulates, is achieved using existing legal authorities that shape how federal action agencies identify, review, mitigate, or otherwise alter their activities based on impacts to natural or cultural resources of National System MPAs. NOAA and DOI believe that given the importance of individual agency authorities in implementing this requirement of Executive Order 13158, no single definition of ''harm'' is possible. The important context of each agency's authorities will govern agencies' analyses of harm, including major versus minor or direct versus indirect harm.

The language in the Executive Order that stipulates that federal agencies avoid harm ''to the maximum extent practicable'' allows for the consideration of important social and economic implications of proposed activities within an MPA. Where appropriate, and upon request by one or more agency, the MPA Center may provide technical assistance (*e.g.,* guidance on best practices), coordination, or facilitation to agencies

seeking to avoid harm to National System MPAs.

Social and Economic Importance of the Marine Environment

Comment: The updated Framework lacks a discussion about the social and economic importance of the marine environment to local communities and economies.

Response: The agencies have modified the Framework to more fully acknowledge the social and economic importance of the marine environment in the section on ''Benefits of an Effective National System'' as well as the introduction.

Role of Regional Planning Bodies

Comment: The updated Framework should not reference linkages between the National System of MPAs in assisting Regional Planning Bodies in potential work to plan new MPAs, as these Bodies have not been established by statute and could unnecessarily restrict access for certain human uses.

Response: Regional Planning Bodies (RPBs) were called for in the Final Recommendations of the Interagency Ocean Policy Task Force, and are a key component of the National Ocean Policy and the Framework for Effective Coastal and Marine Spatial Planning. Insofar as the RPBs, or equivalent regional planning efforts may consider MPAs and other forms of place-based conservation within the broader mosaic of ocean management, NOAA and DOI will provide expertise on MPA issues and provide information and tools to support decisions about place-based management. The Framework has been updated to recognize that regional planning bodies are but one type of regional marine management initiative, and they are referenced as such.

National System of MPAs and Magnuson-Stevens Act

Comment: The updated Framework should clarify that MPAs must be managed in a manner consistent with existing laws. NOAA and DOI should clarify that the concept of ''sustainable fisheries'' is to be implemented within the context of the Magnuson-Stevens Fishery Conservation and Management Act.

Response: The purpose of the updated Framework is to provide a common reference for all federal, state, territorial and tribal programs who wish to participate in the National System of MPAs. As such, it must address all authorities relevant to MPA governance, not solely the Magnuson-Stevens Fishery Conservation and Management Act. The updated Framework makes clear that it is to be implemented in the context of existing authorities.

Monitoring and Evaluation

Comment: Monitoring and evaluation efforts to determine the effectiveness of the current National System of MPAs should be a priority. The MPA Center should provide an analytical basis for identifying which MPAs that are accomplishing their goals and which are not. The MPA Center should publish a biennial ''State of the National System'' report as called for in the Executive Order.

Response: The role of the MPA Center related to monitoring and evaluation is to build the capacity of federal and state marine protected area programs to more effectively manage natural and cultural marine resources, and to serve as a unique and neutral source of marine protected area-related science, information and tools for coastal and ocean decision-makers. Individual MPA programs are responsible for conducting their own monitoring and evaluation, and assessing progress toward program and site-level goals. Periodically, the MPA Center may undertake an evaluation of the National System itself, with the aim of identifying opportunities for improving the collaboration among the nation's MPA programs, including addressing gaps in spatial protection for important areas. For example, in October 2013, the MPA Center published, *Marine Protected Areas of the United States: Conserving Our Oceans, One Place at a Time*—a summary of the state of all US MPAs and of the National System.

Tribal Representation

Comment: The updated Framework should consider including more than one tribal representative to the National System Programs Workgroup. Tribal interests are diverse, and having a single representative appointed to speak for other tribes is a concern.

Response: The updated Framework states that there will be one member of the National System Workgroup for each participating MPA program. Therefore, each tribal government formally participating in the National System of MPAs would have membership on the Workgroup. In addition, the Marine Protected Areas Federal Advisory Committee advises NOAA and DOI on issues related to cultural resource management, including areas managed by and important to tribes, and has established a Cultural Heritage Resources Workgroup to provide expertise on these issues.

Funding

Summary: NOAA should be realistic about what funding will be available and what can be accomplished with existing funding. It should also include an estimate of funding needed to guide implementation of the updated Framework.

Response: NOAA and DOI believe that the updated Framework is not intended to be an implementation plan, and detailed information on funding is not appropriate for this document. The updated Framework does note that implementation of activities will be dependent on levels of funding.

Dated: March 11, 2015.

Daniel J. Basta,

Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2015–07262 Filed 3–27–15; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Interagency Working Group on the Harmful Algal Bloom and Hypoxia Research and Control Amendments Act

AGENCY: National Ocean Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

ACTION: Notice, Webinars.

SUMMARY: The National Ocean Service (NOS) of the National Oceanic and Atmospheric Administration (NOAA) publishes this notice to announce a series of webinars designed to initiate conversation between federal representatives and stakeholders on a number of topics related to harmful algal blooms (HABs) and hypoxia, as mandated by the Harmful Algal Bloom and Hypoxia Research and Control Amendments Act of 2014 (HABHRCA). HABHRCA tasks federal agencies to advance the understanding of HAB and hypoxia events, and to respond to, detect, predict, control, and mitigate these events to the greatest extent possible.

The Interagency Working Group on HABHRCA (IWG–HABHRCA) is comprised of representatives from a number of federal agencies. Through these webinars, the group seeks to connect and speak with a wide range of stakeholders, including relevant management and planning bodies, resource officials, economists, tribal

resource management officials, scientists and public health experts, industries affected by HABs and hypoxia, nonprofit groups, the general public, and others. The IWG–HABHRCA would like to consult with stakeholders on topics such as:

- Regional priorities for ecological, economic, and social research on the causes and impacts of HABs and hypoxia, needs for improved monitoring and early warning, and new approaches to prevention, control, and mitigation;
- Communication and information dissemination methods that state, tribal, and local governments may undertake to educate and inform the public concerning HABs and hypoxia; and
- Perceived needs for handling HAB and hypoxia events, as well as an action strategy for managing future situations.

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

ADDRESSES: See **SUPPLEMENTARY INFORMATION** section for meeting Web addresses.

FOR FURTHER INFORMATION CONTACT: Caitlin Gould (*Caitlin.gould@noaa.gov,* 301–713–3020, x 174) or Stacey DeGrasse (*Stacey.Degrasse@fda.hhs.gov,* 240–402–1470).

SUPPLEMENTARY INFORMATION: NOAA is publishing this notice to announce a series of webinars designed to initiate conversation between federal representatives and stakeholders on a number of topics related to HABs and hypoxia, some of the most scientifically complex and economically damaging issues affecting our ability to safeguard the health of our nation's coastal and freshwater ecosystems. The IWG–HABHRCA was established to coordinate and convene with relevant federal agencies to discuss HAB and hypoxia events in the United States, and to develop a number of reports and assessments of these situations. The webinars are designed to gain information on and discuss what relevant stakeholders perceive to be their needs for handling HAB and hypoxia events, as well as an action strategy for managing future situations. All interested parties are encouraged to attend and participate. As described further below, preregistration is required to participate in these webinars.

Stakeholders are encouraged to submit comments and questions in advance of and following each webinar. Electronic comments and questions may be submitted via email (*IWG–HABHRCA@noaa.gov*). Written comments may be submitted to Caitlin Gould at NOAA, National Centers for Coastal Ocean Science, SSMC–4, #8234, 1305 East-West Highway, Silver Spring, MD 20910.

Meeting dates:

- *National Harmful Algal Bloom and Hypoxia Webinar*—March 26, 2015, 11:30 a.m.–12:30 p.m. EDT
- *Regional Harmful Algal Bloom and Hypoxia Webinar—Southeast/Gulf of Mexico/Mid-Atlantic*—April 2, 2015, 12:30 p.m.–1:30 p.m. EDT
- *Regional Harmful Algal Bloom and Hypoxia Webinar—Inland/Great Lakes*—April 22, 2015, 11:30 a.m.–12:30 p.m. EDT
- *Regional Harmful Algal Bloom and Hypoxia Webinar—Northwest*—April 29, 2015, 2:00 p.m.–3:00 p.m. EDT (11:00 a.m.–12:00 p.m. PDT)
- *Regional Harmful Algal Bloom and Hypoxia Webinar—Northeast*—April 30, 2015, 11:30 a.m.–12:30 p.m. EDT

Real-time remote access to the webinars will be available via the following options:

- *National Harmful Algal Bloom and Hypoxia Webinar*—
  - Internet Webinar Access: *https://fda.webex.com/fda/j.php?MTID=m6e6880abb9f86af5ecba66e01c391612*
    - Password: National
  - To view the webinar in other time zones or languages: *https://fda.webex.com/fda/j.php?MTID=m9a739ad15d3ede13ca70be9894153643*
    - Password: National
  - Teleconference Only Access:
    - Provide your number when you join the meeting to receive a call back.
    - Alternatively, you can call one of the following numbers:
      - Local: *1–301–796–7777*
      - Toll free: *1–855–828–1770*
    - Follow the instructions that you hear on the phone and enter Cisco Unified MeetingPlace meeting ID: 745 274 247
- *Regional Harmful Algal Bloom and Hypoxia Webinar—Southeast/Gulf of Mexico/Mid-Atlantic*—
  - Internet Webinar Access: *https://fda.webex.com/fda/j.php?MTID=m0eac8252e84dd3993a1ea32604d1adf4*
    - Password: Southeast
  - To view the webinar in other time zones or languages: *https://fda.webex.com/fda/j.php?MTID=md5b3388c42c433729d906d6c5622d164*
    - Password: Southeast
  - Teleconference Only Access:
    - Provide your number when you join the meeting to receive a call back.
    - Alternatively, you can call one of the following numbers:
      - Local: *1–301–796–7777*
      - Toll free: *1–855–828–1770*
    - Follow the instructions that you hear on the phone and enter Cisco Unified MeetingPlace meeting ID: 749 761 616
- *Regional Harmful Algal Bloom and Hypoxia Webinar—Inland/Great Lakes*—
  - Internet Webinar Access: *https://fda.webex.com/fda/j.php?MTID=mf98ac949c431ffe04b674057de8bd809*
    - Password: Inland
  - To view the webinar in other time zones or languages: *https://fda.webex.com/fda/j.php?MTID=m1729f80ba875d8f87a0c5661d354529a*
    - Password: Inland
  - Teleconference Only Access:
    - Provide your number when you join the meeting to receive a call back.
    - Alternatively, you can call one of the following numbers:
      - Local: *1–301–796–7777*
      - Toll free: *1–855–828–1770*
    - Follow the instructions that you hear on the phone and enter Cisco Unified MeetingPlace meeting ID: 741 855 825
- *Regional Harmful Algal Bloom and Hypoxia Webinar—Northwest*—
  - Internet Webinar Access: *https://fda.webex.com/fda/j.php?MTID=m4e9bb6ef61d4f8257486d29884ff67e0*
    - Password: Northwest
  - To view the webinar in other time zones or languages: *https://fda.webex.com/fda/j.php?MTID=mea7088d04482f51a0ab659e6d9564e24*
    - Password: Northwest
  - Teleconference Only Access:
    - Provide your number when you join the meeting to receive a call back.
    - Alternatively, you can call one of the following numbers:
      - Local: *1–301–796–7777*
      - Toll free: *1–855–828–1770*
    - Follow the instructions that you hear on the phone and enter Cisco Unified MeetingPlace meeting ID: 748 981 584
- *Regional Harmful Algal Bloom and Hypoxia Webinar—Northeast*
  - Internet Webinar Access: *https://fda.webex.com/fda/j.php?MTID=m3bde49b5ce0994462f9aae9e330e1438*
    - Password: Northeast
  - To view the webinar in other time zones or languages: *https://fda.webex.com/fda/j.php?MTID=m72ded81789dedac878c7ad13429751b3*
    - Password: Northeast
  - Teleconference Only Access:
    - Provide your number when you join the meeting to receive a call back.
    - Alternatively, you can call one of the following numbers:
      - Local: *1–301–796–7777*
      - Toll free: *1–855–828–1770*
    - Follow the instructions that you hear on the phone and enter Cisco Unified MeetingPlace meeting ID: 744 725 401

Persons wishing to attend the meeting online via the webinar must register in

advance no later than 5 p.m. Eastern Time on the evening before each webinar, by sending an email to *Caitlin.Gould@noaa.gov.* The number of webinar connections available for the meetings is limited to 500 participants and will therefore be available on a first-come, first-served basis. The agenda for the webinars will include time for questions and answers or comments about the agencies' efforts in implementing HABHRCA.

Other Information:

Paperwork Reduction Act: Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection displays a currently valid OMB Control Number.

Dated: March 24, 2015.

Mary Erickson,

Director, National Centers for Coastal Ocean Science, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2015–07247 Filed 3–27–15; 8:45 am]

BILLING CODE 3510–JE–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–836]

Certain Cut-To-Length Carbon-Quality Steel Plate from the Republic of Korea: Initiation of Antidumping Duty New Shipper Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* March 30, 2015.

SUMMARY: The Department of Commerce (the Department) received a timely request for a new shipper review of the antidumping duty order on certain cut-to-length carbon-quality steel plate from the Republic of Korea. The Department has determined that the request meets the statutory and regulatory requirements for initiation.

FOR FURTHER INFORMATION CONTACT: Thomas Schauer, AD/CVD Operations Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; Telephone: (202) 482–0410.

SUPPLEMENTARY INFORMATION:

Background

The antidumping duty order on certain cut-to-length carbon-quality steel plate from the Republic of Korea published in the **Federal Register** on February 10, 2000.[1] Pursuant to section 751(a)(2)(B)(i) of the Tariff Act of 1930, as amended (the Act), we received a timely request for a new shipper review of the order from Hyundai Steel Co., Ltd. (Hyundai).[2] Hyundai certified that it is both the producer and exporter of the subject merchandise upon which the request was based.[3]

Pursuant to section 751(a)(2)(B)(i)(I) of the Act and 19 CFR 351.214(b)(2)(i), Hyundai certified that it did not export subject merchandise to the United States during the period of investigation (POI).[4] In addition, pursuant to section 751(a)(2)(B)(i)(II) of the Act and 19 CFR 351.214(b)(2)(iii)(A), Hyundai certified that, since the initiation of the investigation, it has never been affiliated with any exporter or producer who exported subject merchandise to the United States during the POI, including those respondents not individually examined during the POI.[5]

In addition to the certifications described above, pursuant to 19 CFR 351.214(b)(2), Hyundai submitted documentation establishing the following: (1) The date on which it first shipped subject merchandise for export to the United States; (2) the volume of its first shipment; and (3) the date of its first sale to an unaffiliated customer in the United States.[6]

Period of Review

In accordance with 19 CFR 351.214(g)(1)(i)(A) of the Act, the period of review (POR) for new shipper reviews initiated in the month immediately following the anniversary month will be the twelve-month period immediately preceding the anniversary month. Therefore, under this order, the POR is February 1, 2014, through January 31, 2015.

Initiation of New Shipper Review

Pursuant to section 751(a)(2)(B) of the Act and 19 CFR 351.214(d)(1), the Department finds that the request from Hyundai meets the threshold requirements for initiation of a new shipper review for shipments of certain cut-to-length carbon-quality steel plate from the Republic of Korea produced and exported by Hyundai.[7]

The Department intends to issue the preliminary results of this new shipper review no later than 180 days from the date of initiation and final results of the review no later than 90 days after the date the preliminary results are issued.[8]

We will instruct U.S. Customs and Border Protection to allow, at the option of the importer, the posting, until the completion of the review, of a bond or security in lieu of a cash deposit for each entry of the subject merchandise from Hyundai in accordance with section 751(a)(2)(B)(iii) of the Act and 19 CFR 351.214(e). Because Hyundai certified that it produced and exported subject merchandise, the sale of which is the basis for the request for a new shipper review, we will apply the bonding privilege to Hyundai only for subject merchandise which was produced and exported by Hyundai.

To assist in its analysis of the *bona fides* of Hyundai's sales, upon initiation of this new shipper review, the Department will require Hyundai to submit on an ongoing basis complete transaction information concerning any sales of subject merchandise to the United States that were made subsequent to the POR.

Interested parties requiring access to proprietary information in the new shipper review should submit applications for disclosure under administrative protective order in accordance with 19 CFR 351.305 and 351.306.

This initiation and notice are published in accordance with section 751(a)(2)(B) of the Act and 19 CFR 351.214 and 351.221(c)(1)(i).

Dated: March 24, 2015.

Gary Taverman,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2015–07198 Filed 3–27–15; 8:45 am]

BILLING CODE 3510–DS—P

[1] *See Notice of Amendment of Final Determinations of Sales at Less Than Fair Value and Antidumping Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate Products From France, India, Indonesia, Italy, Japan and the Republic of Korea,* 65 FR 6585 (February 10, 2000) (*Order*).

[2] *See* Hyundai's new shipper request dated February 27, 2015.

[3] *Id.,* at Exhibit 1.

[4] *Id.*

[5] *Id.*

[6] *Id.,* at Exhibits 1, 2, and 3.

[7] *See* the memorandum to the file entitled ''Certain Cut-To-Length Carbon-Quality Steel Plate from the Republic of Korea: Initiation Checklist for Antidumping Duty New Shipper Review of Hyundai Steel Co., Ltd.'' dated concurrently with this notice.

[8] *See* section 751(a)(2)(B)(iv) of the Act.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Western Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Western Pacific Fishery Management Council (Council) will hold meetings of its Joint Hawaii, Marianas and American Samoa Archipelago Plan Team (Joint PT) and the Council's Fishery Data Collection and Research Committee—Technical Committee (FDCRC–TC). The Joint PT will review the status of the nearshore fisheries, data collection and research issues and improvements, evaluation of the 2014 catch and Annual Catch Limit (ACL) specifications, developing a Cooperative Research framework and review the essential fish habitat (EFH) and habitat area of particular concern criteria for the Western Pacific Region. The FDCRC–TC will review the status of the data collection projects, determine priority tasks, schedule, and assignments as well as develop an omnibus FDCRC proposal.

DATES: The Joint PT meeting on April 14, 2015, and the FDCRC–TC meeting April 16–17, 2015. For specific times and agendas, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The Joint PT and FDCRC–TC meetings will be held at the Council office, 1164 Bishop Street, Suite 1400, Honolulu, HI 96813; telephone: (808) 522–8220.

FOR FURTHER INFORMATION CONTACT: Kitty M. Simonds, Executive Director; telephone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: Public comment periods will be provided. The order in which agenda items are addressed may change. The meetings will run as late as necessary to complete scheduled business.

Schedule and Agenda for the Joint PT Meeting

April 14, 2015—8:30 a.m.–5 p.m.

1. Welcome and introductions
2. Approval of draft agenda & assignment of rapporteurs
3. Report on previous Plan Team recommendations and Council actions
4. 2014 annual report modules
   A. American Samoa coral reef, crustacean and bottomfish fishery
   B. Guam coral reef, crustacean and bottomfish fishery
   C. CNMI coral reef, crustacean and bottomfish fishery
   D. Hawaii coral reef, crustacean, and bottomfish fishery
5. Annual Catch Limits
   A. Evaluating 2014 catches to its respective 2014 ACLs (Action Item)
   B. Discussions
   C. Public Comment
6. Report on Data Collection and Research Projects
   A. Seasonal run fishery data collection
   B. Improving commercial vendor reporting
   C. Abundance estimation of Hawaii akule using aerial surveys
   D. Determining biological reference points
   E. Productivity and susceptibility analysis of the coral reef fisheries
   F. Discussions
   G. Public Comment
7. Update Cooperative Research and developing priorities
   A. Background on NMFS Cooperative Research Program
   B. Developing a framework for Cooperative Research in WP region
   C. Discussions
   D. Public Comment
8. Review of the Essential Fish Habitat and Habitat Areas of Particular Concern Science Review and PIRO Recommendations
   A. Background and current status
   B. Options for HAPC Designation—Application of EFH Final Rule Considerations
   C. Discussions
   D. Public Comment
9. General Discussions
10. Archipelagic Plan Team Recommendations
11. Other Business

Schedule and Agenda for the FDCRC–TC Meeting:

April 16, 2015—8:30 a.m.–5 p.m.

1. Welcome and introductions
2. Approval of draft agenda
3. Report on accomplishments from the last FDCRC–TC meeting
4. Report on Data Collection and Research Projects
   A. Seasonal run fishery data collection
   B. Improving commercial vendor reporting
   C. Status of CNMI data collection projects
   i. Tinian fishery data collection
   ii. Mandatory reporting
   iii. Fishery Information System electronic reporting
   D. Status of the AS and CNMI genetic projects
   E. Determining essential fish habitat for coral reef fish
5. Moving towards a comprehensive database system and modern day reporting
   A. Alaska Fishery Information Network: engine for science and management
   B. Digital Deck: Utilizing mobile technology for reporting catch
   C. SHINYAPP: Flexibility in report generation
   D. Discussions
   E. Public Comment
6. Review of the strategic plan and taking the step forward
   A. Species and fishery prioritization
   B. Funding source identification
   C. Prioritizing tasks
   D. Assignment of funding source
7. General Discussions
8. Archipelagic FDCRC Technical Committee Recommendations
9. Other Business

April 17, 2015—8:30 a.m.–5 p.m.

10. Work session overview
    A. Coverage of the work session
    B. Sample proposals and funding FFOs
    C. Project assignment
11. Drafting of project narratives
12. Developing timelines and performance monitoring standards
13. Adjourn

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

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

Dated: March 25, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–07156 Filed 3–27–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD847

Fisheries of the South Atlantic; South Atlantic Fishery Management Council; Public Meeting

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

ACTION: Notice of a meeting.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold a meeting of its King and Spanish Mackerel Advisory Panel (AP) in North Charleston, SC. The meeting is open to the public.

DATES: The meeting will be held from 9 a.m. until 5 p.m. on Wednesday, April 15, 2015.

ADDRESSES:

Meeting address: The meeting will be held at the Hilton Garden Inn, 5265 International Blvd., N. Charleston, SC 29418; telephone: (843) 308–9330.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405; telephone: (843) 571–4366 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: The King and Spanish Mackerel AP will receive updates on recent amendments to the Coastal Migratory Pelagics Fishery Management Plan for the Gulf of Mexico and the South Atlantic (Mackerel FMP). The AP will receive an update on Amendment 26 to the Mackerel FMP that includes alternatives for revisions to the annual catch limits and stock management boundary for king mackerel and to allow the sale of king mackerel bycatch in the shark gillnet fishery. The AP will also receive a presentation on electronic reporting and review the Generic Charterboat Reporting Amendment. Additionally, the AP will be briefed on genetic research on South Carolina sub-populations of cobia. The AP will provide recommendations as appropriate and address other business as necessary.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 3 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Dated: March 25, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–07175 Filed 3–27–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Amended Order Temporarily Denying Export Privileges

Flider Electronics, LLC a/k/a Flider Electronics d/b/a Trident International Corporation d/b/a Trident International d/b/a Trident International Corporation, LLC, 837 Turk Street, San Francisco, California 94102

and

Pavel Semenovich Flider a/k/a Pavel Flider, 21 Eye Street, San Rafael, California 94901

and

Gennadiy Semenovich Flider a/k/a Gennadiy Flider, 699 36th Avenue #203, San Francisco, California 94121

Pursuant to Section 766.24 of the Export Administration Regulations (the ''Regulations'' or ''EAR''),[1] the Bureau of Industry and Security (''BIS''), U.S. Department of Commerce, through its Office of Export Enforcement (''OEE''), has requested that I issue an Order temporarily denying, for a period of 180 days, the export privileges of Flider Electronics, LLC, also known as Flider Electronics, and doing business as Trident International Corporation, Trident International, and Trident International Corporation, LLC. Flider Electronics, LLC is a California limited liability company based in San Francisco, California. It is operated, at least in substantial part, for the purpose of procuring and exporting U.S.-origin electronic components. California State Corporation Number C1908339 has been used in connection with the doing business names of Trident International Corporation, Trident International, and Trident International Corporation, LLC, but that number is associated with Flider Electronics, LLC and the address used in connection with those doing business as names is the same address as Flider Electronics, LLC. Pavel Semenovich Flider, also known as Pavel Flider, is the president and owner of Flider Electronics/Trident International (''Trident''). His brother Gennadiy Semenovich Flider, also known as Gennadiy Flider, has identified himself as Trident's office manager, since 2003, and his duties include the purchase of items from U.S. distributors, the shipment of those items abroad, and related filings with U.S. Government agencies.[2]

Pursuant to Section 766.24, BIS may issue an order temporarily denying a respondent's export privileges upon a showing that the order is necessary in the public interest to prevent an ''imminent violation'' of the Regulations. 15 CFR 766.24(b)(1) and 776.24(d). ''A violation may be 'imminent' either in time or degree of likelihood.'' 15 CFR 766.24(b)(3). BIS may show ''either that a violation is about to occur, or that the general circumstances of the matter under investigation or case under criminal or administrative charges demonstrate a likelihood of future violations.'' *Id.* As to the likelihood of future violations, BIS may show that the violation under investigation or charge ''is significant, deliberate, covert and/or likely to occur again, rather than technical or negligent [.]'' *Id.* A ''lack of information establishing the precise time a violation may occur does not preclude a finding that a violation is imminent, so long as there is sufficient reason to believe the likelihood of a violation.'' *Id.*

In its request, OEE has presented evidence that it has reason to believe that Trident engaged in conduct prohibited by the Regulations by exporting items subject to the EAR to Russia via transshipment through third countries. In Automated Export System (''AES'') filings it made, Trident identified as ''ultimate consignees'' companies in Estonia and Finland that BIS has reason to believe were operating as freight forwarders and not end users of the U.S.-origin items. OEE's presentation also indicates that at least two of these transactions are known to have involved items that are listed on the Commerce Control List and that a search of BIS's licensing database reveals no licensing history of controlled U.S.-origin electronics to Russia for the company and individuals captioned in this case. Based on, inter alia, the transshipment of the items, the misrepresentations made on the AES filings, and information obtained pursuant to a Mutual Legal Assistance Treaty (''MLAT'') request, OEE indicates that it has reason to believe that these exports required a license.

[1] The Regulations are currently codified at 15 CFR parts 730–774 (2014). The EAR issued under the Export Administration Act of 1979, as amended (50 U.S.C. app. §§ 2401–2420 (2000)) (''EAA''). Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 7, 2014 (79 FR 46959 (Aug. 11, 2014)), has continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701, *et seq.*) (2006 & Supp. IV 2010).

[2] I approved OEE's request and issued a temporary denial order against Trident on March 19, 2015. Pavel Flider and Gennadiy Flider were added to that order, as issued, as related persons to Trident. This amended order makes limited revision to page 6 of the March 19, 2015 order, and does not change my findings or the terms of the order issued on March 19, 2015. *See* pp. 6–11, *infra.*

A. Detained Shipments on April 6, 2013

On or about April 6, 2013, the U.S. Customs and Border Protection (''CBP'') detained two outbound shipments at San Francisco International Airport. CBP ultimately allowed one of these exports to proceed, but the other attempted export was not and the items were ultimately seized. The manifest and the AES filing for the seized shipment described the items as ''power supplies,'' but the shipment actually contained, among other items, 15 Xilinx field programmable gate array (FPGA) circuits that were controlled under Export Control Classification Number (ECCN) 3A001.a.2.c for national security reasons and generally required a license for Russia. The shipping documentation also listed Logilane Oy Ltd. in Finland (''Logilane'') as the ultimate consignee. Open source information confirmed that Logilane was a freight forwarder and thus unlikely to be the end user for the items contained in the shipment. When questioned about the shipment, Pavel Flider requested that the ultimate consignee be changed to Adimir OU (''Adimir'') in Estonia, which itself also proved to be a freight forwarder as discussed further below.

B. Interviews of Pavel Flider and Gennadiy Flider

On or about April 19, 2013, OEE interviewed Trident office manager Gennadiy Flider, who identified his responsibilities as handling the procurement and shipment of items, including for export. He stated Trident had been doing business with Adimir for many years and that it was the only customer that his company had. He also indicated that Trident at times shipped items intended for its Estonian customer to Finland, claiming this was because it was cheaper.

Similarly, in an August 5, 2013 interview, Trident's president and owner Pavel Flider stated that Adimir was Trident's one and only customer and that at times Adimir requested that items be shipped to a freight forwarder in Finland. Both Gennadiy Flider and Pavel Flider denied shipping to Russia.

C. July 2013 Detention and Subsequent Seizure

On or about July 20, 2013, the U.S. Government detained a Trident shipment bound for Adimir in Estonia. In addition to Adimir being identified as the ultimate consignee on the AES filing, the items were identified as ''Electronic Equipment.'' A review of the invoice showed six Xilinx FPGAs, items which were controlled under ECCN 3A001.a.2.c for national security reasons and generally required a license for Russia. Moreover, an inspection of the shipment uncovered 51 controlled Xilinx chips, rather than just the six that had been declared. CBP ultimately seized the shipment on or about October 18, 2013.

D. Information Concerning Purported Estonian End User Obtained via an MLAT Request

Based on information obtained in 2014 via a late 2013 MLAT request sent to Estonia relating to Adimir, BIS has reason to believe that Adimir was not an end user. During an interview, an Adimir corporate officer admitted to transshipping Trident shipments to Russia at the request of Pavel Flider. Adimir subsequently ceased operating.

E. Changes in the Scheme

Following the detention and seizures, the MLAT request, and the Adimir interview, Trident began exporting directly to Russia, claiming that the controlled circuits were for use in railroads. This assertion sought to track a note to ECCN 3A001.a.2, which indicates that the ECCN does not apply to integrated circuits for civil automotive or railway train applications. Pavel Flider reported to the U.S. distributor that Trident had been ''referred'' Russian customers by Adimir, which was going out of business. After being made aware that the items actually were intended for export to Russia, the U.S. distributor requested that Trident sign a Form BIS–711 ''Statement by Ultimate Consignee and Purchaser,'' which includes an end use statement and must be signed by the purchaser and the ultimate consignee.

From on or about January 23, 2014, to on or about April 16, 2014, Trident began listing in its AES filings OOO Elkomtex (''Elkomtex'') in St. Petersburg, Russia, as the ultimate consignee. On or about July 17, 2014, the Elkomtex employees admitted that the company was not an end user but a distributor of electronics, acting as a broker between an exporter and an end use company.

Beginning with an export on or about May 6, 2014, Trident again changed its export route and began exporting to a purported ultimate consignee named Logimix Ltd., in Vantaa, Finland (''Logimix''). Between on or about May 6, 2014, to on or about March 12, 2015, AES filings indicate that Trident has made 33 exports with Logimix listed as the ultimate consignee. Based on Logimix's Web site and other open source Internet information, however, OEE's presentation indicates that it has reason to believe that Logimix is a freight forwarder and not an end user. Moreover, given the violations, deceptive actions, and other evidence involving Trident, including those admitted by the Fliders, OEE also indicates that it has reason to believe that Trident have been making transshipments to Russia.

OEE has further indicated that in February 2014, Trident ordered an additional 195 integrated circuits controlled under ECCN 3A001.a.2.c from a U.S. distributor and that those items would be available by in or around April 2015. In addition, Trident and Pavel Flider have been indicted for smuggling and money laundering, including in connection with some of the transactions discussed above. The U.S. Government also seized multiple accounts in which Trident had an interest.

F. Findings

I find that the evidence presented by BIS demonstrates that a violation of the Regulations is imminent in both time and degree of likelihood. Trident has engaged in some known violations of the Regulations and its actions, including changes in how it structures its export transactions and routes its shipments, appear designed to camouflage the actual destinations, end uses, and/or end users of the U.S.-origin items it has been and continues to export, including items on the Commerce Control List that are subject to national security-based license requirements. Moreover, when interviewed in 2013, the Fliders could not provide a reasonable explanation for the purported exports to Estonia and Finland. When for a time Trident began direct exports to Russia, the entity listed as the ultimate consignee admitted that it was not an end user and instead acting as a broker.

In sum, the fact and circumstances taken as a whole provide strong indicators that future violations are likely absent the issuance of a TDO. As such, a TDO is needed to give notice to persons and companies in the United States and abroad that they should cease dealing with Trident in export transactions involving items subject to the EAR. Such a TDO is consistent with the public interest to preclude future violations of the EAR.

Additionally, Section 766.23 of the Regulations provides that ''[i]n order to prevent evasion, certain types of orders under this part may be made applicable not only to the respondent, but also to other persons then or thereafter related to the respondent by ownership, control, position of responsibility, affiliation, or other connection in the

conduct of trade or business. Orders that may be made applicable to related persons include those that deny or affect export privileges, including temporary denial orders. . . .'' 15 CFR 766.23(a). As stated above, Pavel Flider is the president and owner of Trident. Gennadiy Flider also is a Trident office manager, with responsibilities relating directly to the procurement and export activities at issue. As such, I find that Pavel Semenovich Flider and Gennadiy Semenovich Flider are related persons to Trident based on their positions of responsibility and that their additions to the order is necessary to prevent evasion.

Accordingly, I find that an order denying the export privileges of Trident, Pavel Flider, and Gennadiy Flider is necessary, in the public interest, to prevent an imminent violation of the EAR.

This Order is being issued on an *ex parte* basis without a hearing based upon BIS's showing of an imminent violation in accordance with Section 766.24 of the Regulations.

It is therefore ordered:

First, that FLIDER ELECTRONICS, LLC, a/k/a FLIDER ELECTRONICS, d/b/a TRIDENT INTERNATIONAL CORPORATION, d/b/a TRIDENT INTERNATIONAL d/b/a TRIDENT INTERNATIONAL CORPORATION, LLC, 837 Turk Street, San Francisco, California 94102; PAVEL SEMENOVICH FLIDER, a/k/a PAVEL FLIDER, 21 Eye Street, San Rafael, California 94901; and GENNADIY SEMENOVICH FLIDER, a/k/a GENNADIY FLIDER, 699 36th Avenue #203, San Francisco, California 94121, and when acting for or on their behalf, any successors or assigns, agents, or employees (each a ''Denied Person'' and collectively the ''Denied Persons'') may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the Export Administration Regulations (''EAR''), or in any other activity subject to the EAR including, but not limited to:

A. Applying for, obtaining, or using any license, License Exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or in any other activity subject to the EAR; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or in any other activity subject to the EAR.

Second, that no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of a Denied Person any item subject to the EAR;

B. Take any action that facilitates the acquisition or attempted acquisition by a Denied Person of the ownership, possession, or control of any item subject to the EAR that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby a Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from a Denied Person of any item subject to the EAR that has been exported from the United States;

D. Obtain from a Denied Person in the United States any item subject to the EAR with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the EAR that has been or will be exported from the United States and which is owned, possessed or controlled by a Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by a Denied Person if such service involves the use of any item subject to the EAR that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, that, after notice and opportunity for comment as provided in Section 766.23 of the EAR, any other person, firm, corporation, or business organization related to a Denied Person by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order.

In accordance with the provisions of Section 766.24(e) of the EAR, Flider Electronics, LLC d/b/a Trident International Corporation, may, at any time, appeal this Order by filing a full written statement in support of the appeal with the Office of the Administrative Law Judge, U.S. Coast Guard ALJ Docketing Center, 40 South Gay Street, Baltimore, Maryland 21202–4022. In accordance with the provisions of Sections 766.23(c)(2) and 766.24(e)(3) of the EAR, Pavel Semenovich Flider and Gennadiy Semenovich Flider may, at any time, appeal their inclusion as a related person by filing a full written statement in support of the appeal with the Office of the Administrative Law Judge, U.S. Coast Guard ALJ Docketing Center, 40 South Gay Street, Baltimore, Maryland 21202–4022.

In accordance with the provisions of Section 766.24(d) of the EAR, BIS may seek renewal of this Order by filing a written request not later than 20 days before the expiration date. Flider Electronics, LLC d/b/a Trident International Corporation may oppose a request to renew this Order by filing a written submission with the Assistant Secretary for Export Enforcement, which must be received not later than seven days before the expiration date of the Order.

A copy of this Order shall be sent to Flider Electronics LLC d/b/a Trident International Corporation and each related person, and shall be published in the **Federal Register**.

This Order is effective upon issuance and shall remain in effect until September 14, 2015.

Dated: March 23, 2015.

David W. Mills,

Assistant Secretary of Commerce for Export Enforcement.

[FR Doc. 2015–07181 Filed 3–27–15; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–840, A–549–822]

Certain Frozen Warmwater Shrimp From India and Thailand: Notice of Initiation of Antidumping Duty Administrative Reviews

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) received requests to conduct administrative reviews of the antidumping duty (AD) orders on certain frozen warmwater shrimp (shrimp) from India and Thailand for the period February 1, 2014 through January 31, 2015. The anniversary month of these orders is February. In accordance with the Department's regulations, we are initiating these administrative reviews. The Department also received a request to defer the initiation of the administrative review for the order on shrimp from Thailand with respect to various Thai companies.

DATES: *Effective Date:* March 30, 2015.

FOR FURTHER INFORMATION CONTACT: Blaine Wiltse at (202) 482–6345 (India)

and Dennis McClure (202) 482–5973 (Thailand), AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

During the anniversary month of February 2015, the Department received timely requests, in accordance with 19 CFR 351.213(b), for administrative reviews of the AD orders on shrimp from India and Thailand from the Ad Hoc Shrimp Trade Action Committee (hereinafter, the petitioner), the American Shrimp Processors Association (ASPA), and certain individual companies.

All deadlines for the submission of various types of information, certifications, or comments or actions by the Department discussed below refer to the number of calendar days from the applicable starting time.

Request To Defer Review of the AD Order on Shrimp From Thailand

In their requests for administrative review, various Thai companies requested that the Department defer the initiation of the review for one year, pursuant to 19 CFR 351.213(c). These companies are identified by a * in the ''Initiation of Reviews'' section of this notice, below. The parties requested the deferral to reduce the burden on the companies and on the Department.

The Department's regulations, as set forth in 19 CFR 351.213(c)(1)(i) and (ii), provide that the Department may defer the initiation of an antidumping duty administrative review, in whole or in part, for one year if: (1) The request for review was accompanied by a request to defer the review; and (2) neither the exporter or producer for which the deferral is requested, the importer of subject merchandise from that exporter or producer, nor a domestic interested party objects to the deferral. On March 13, 2015, the petitioner submitted a timely-filed objection to deferring the initiation of this administrative review, pursuant to 19 CFR 351.213(c)(2).[1]

The preamble to the Department's regulations states that the Department established the provision for deferring the initiation of an administrative review, in part, to reduce burdens on the Department.[2] We believe that deferring the instant review is not likely to save Departmental resources because it is likely that, in this review, as in every prior administrative review of the AD order on shrimp from Thailand,[3] the Department will find it necessary to limit the number of respondents examined. Accordingly, even if the Department defers the administrative review for these companies, it will likely still review the same number of respondents, *i.e.,* the maximum number of respondents which our resources will permit. Therefore, we have not deferred the instant review for any companies requesting deferral with respect to the AD order on shrimp from Thailand.

Notice of No Sales

If a producer or exporter named in this notice of initiation had no exports, sales, or entries during the period of review (POR), it must notify the Department within 60 days of publication of this notice in the **Federal Register**. All submissions must be filed electronically at *http://access.trade.gov* in accordance with 19 CFR 351.303.[4] Such submissions are subject to verification in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act). Further, in accordance with 19 CFR 351.303(f)(1)(i), a copy must be served on every party on the Department's service list.

Respondent Selection

In the event the Department limits the number of respondents for individual examination in the administrative review of the AD orders on shrimp from India and Thailand, the Department intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the POR. We intend to release the CBP data under Administrative Protective Order (APO) to all parties having an APO within seven days of publication of this initiation notice and to make our decision regarding respondent selection within 21 days of publication of this **Federal Register** notice. 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 applicable review. Rebuttal comments will be due five days after submission of initial comments.

In general, the Department has found 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 collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of these antidumping proceedings (*i.e.,* investigation, administrative review, or changed circumstances review). For any company subject to these reviews, 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. 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.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that has requested 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 the Department does not intend to extend the 90-day deadline unless the requestor demonstrates that an extraordinary circumstance has 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.

Requests for Reviews of Non-Shrimp Producers/Exporters

In the 2011–2012 administrative review of shrimp from Thailand, the

[1] *See* the petitioner's March 13, 2015, letter.

[2] *See Antidumping Duties; Countervailing Duties; Final Rule,* 62 FR 27296, 27317 (May 19, 1997).

[3] *See, e.g., Certain Frozen Warmwater Shrimp From Thailand; Preliminary Results of Antidumping Duty Administrative Review, Partial Rescission of Review, Preliminary Determination of No Shipments; 2012–2013,* 79 FR 15951 (March 24, 2014), unchanged in *Certain Frozen Warmwater Shrimp From Thailand: Final Results of Antidumping Duty Administrative Review, Final Determination of No Shipments, and Partial Rescission of Review; 2012–2013,* 79 FR 51306 (August 28, 2014) (*2012–2013 Thai Shrimp*); and *Certain Frozen Warmwater Shrimp From Thailand: Preliminary Results of Antidumping Duty Administrative Review and Intent To Revoke the Order (in Part); 2011–2012,* 78 FR 15686 (March 12, 2013), unchanged in *Certain Frozen Warmwater Shrimp From Thailand: Final Results of Antidumping Duty Administrative Review, Partial Rescission of Review, and Revocation of Order (in Part); 2011–2012,* 78 FR 42497, 42498–42499 (July 16, 2013) (*2011–2012 Thai Shrimp*).

[4] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

Department found that Kosamut Frozen Foods Co., Ltd. (Kosamut) and Tanaya International Co., Ltd./Tanaya Intl (collectively, Tanaya) were neither exporters nor producers of the subject merchandise, as defined in 19 CFR 351.213(b) and 351.102(b)(29)(i). Accordingly, we rescinded the review for these companies, pursuant to 19 CFR 351.213(d)(3).[5] Therefore, based upon that determination, we are not initiating an administrative review with respect to Kosamut or Tanaya for the current POR absent specific information that the companies at issue are exporters or producers of the subject merchandise.

In the 2013–2014 administrative review of shrimp from Thailand, the Department did not initiate a review with respect to GSE Lining Technology Co., Ltd. because the company neither produced nor exported shrimp.[6] Therefore, we are not initiating an administrative review with respect to this company for the current POR.

Initiation of Reviews

In accordance with 19 CFR 351.221(c)(1)(i), we are initiating administrative reviews of the antidumping duty orders on shrimp from India and Thailand. We intend to issue the final results of these reviews not later than March 9, 2016.

	Period to be reviewed
Antidumping Duty Proceedings	
India: Certain Frozen Warmwater Shrimp, A–533–840	2/1/14–1/31/15
Abad Fisheries	
Adilakshmi Enterprises	
Akshay Food Impex Private Limited	
Allana Frozen Foods Pvt. Ltd.	
Allanasons Ltd.	
AMI Enterprises	
Amulya Sea Foods	
Anand Aqua Exports	
Ananda Aqua Applications/Ananda Aqua Exports (P) Limited/Ananda Foods	
Ananda Enterprises (India) Private Limited	
Andaman Sea Foods Pvt. Ltd.	
Angelique Intl	
Anjaneya Seafoods	
Apex Frozen Foods Private Limited[7]	
Aquatica Frozen Foods Global Pvt. Ltd.	
Arvi Import & Export	
Asvini Exports	
Asvini Fisheries Private Limited	
Avanti Feeds Limited	
Ayshwarya Seafood Private Limited	
B R Traders	
Baby Marine Exports	
Baby Marine International	
Baby Marine Sarass	
Balasore Marine Exports Private Limited	
Bhatsons Aquatic Products	
Bhavani Seafoods	
Bijaya Marine Products	
Blue Fin Frozen Foods Pvt. Ltd.	
Blue Water Foods & Exports P. Ltd.	
Bluepark Seafoods Private Ltd.	
BMR Exports	
BMR Industries Private Limited	
Britto Exports	
C P Aquaculture (India) Ltd.	
Calcutta Seafoods Pvt. Ltd.	
Canaan Marine Products	
Capithan Exporting Co.	
Castlerock Fisheries Ltd.	
Chemmeens (Regd)	
Cherukattu Industries (Marine Div.)	
Choice Canning Company	
Choice Trading Corporation Private Limited	
Coastal Aqua	
Coastal Corporation Ltd.	
Cochin Frozen Food Exports Pvt. Ltd.	
Coreline Exports	
Corlim Marine Exports Pvt. Ltd.	
D2 D Logistics Private Limited	
Damco India Private Limited	
Delsea Exports Pvt. Ltd.	
Devi Fisheries Limited/Satya Seafoods Private Limited/Usha Seafoods	
Devi Marine Food Exports Private Ltd./Kader Exports Private Limited/Kader Investment and Trading Company Private Limited/Liberty Frozen Foods Pvt. Ltd./Liberty Oil Mills Ltd./Premier Marine Products Private Limited[8]/ Universal Cold Storage Private Limited	

[5] *See 2011–2012 Thai Shrimp,* 78 FR at 42498–42499.

[6] *See Certain Frozen Warmwater Shrimp From India and Thailand: Notice of Initiation of Antidumping Duty Administrative Reviews,* 79 FR 18510 (April 2, 2014).

	Period to be reviewed
Diamond Seafoods Exports/Edhayam Frozen Foods Pvt. Ltd./Kadalkanny Frozen Foods/Theva & Company	
Devi Sea Foods Limited [9]	
Digha Seafood Exports	
Esmario Export Enterprises	
Exporter Coreline Exports	
Falcon Marine Exports Limited/K.R. Enterprises	
Febin Marine Foods	
Five Star Marine Exports Private Limited	
Forstar Frozen Foods Pvt. Ltd.	
Frontline Exports Pvt. Ltd.	
G A Randerian Ltd.	
Gadre Marine Exports	
Galaxy Maritech Exports P. Ltd.	
Gayatri Seafoods	
Geo Aquatic Products (P) Ltd.	
Geo Seafoods	
Goodwill Enterprises	
Grandtrust Overseas (P) Ltd.	
GVR Exports Pvt. Ltd.	
Haripriya Marine Export Pvt. Ltd.	
Harmony Spices Pvt. Ltd.	
HIC ABF Special Foods Pvt. Ltd.	
Hindustan Lever, Ltd.	
Hiravata Ice & Cold Storage	
Hiravati Exports Pvt. Ltd.	
Hiravati International P. Ltd. (located at APM—Mafco Yard, Sector—18, Vashi, Navi, Mumbai—400 705, India)	
Hiravati International Pvt. Ltd. (located at Jawar Naka, Porbandar, Gujarat, 360 575, India)	
IFB Agro Industries Ltd.	
Indian Aquatic Products	
Indo Aquatics	
Indo Fisheries	
Indo French Shellfish Company Private Limited	
Innovative Foods Limited	
International Freezefish Exports	
Interseas	
ITC Limited, International Business	
ITC Ltd.	
Jagadeesh Marine Exports	
Jaya Satya Marine Exports	
Jaya Satya Marine Exports Pvt. Ltd.	
Jayalakshmi Sea Foods Private Limited	
Jinny Marine Traders	
Jiya Packagings	
K R M Marine Exports Ltd.	
K V Marine Exports	
Kalyan Aqua & Marine Exports India Pvt. Ltd.	
Kalyanee Marine	
Kanch Ghar	
Karunya Marine Exports Private Limited	
Kay Kay Exports	
Kings Marine Products	
Koluthara Exports Ltd.	
Konark Aquatics & Exports Pvt. Ltd.	
Landauer Ltd.	
Libran Cold Storages (P) Ltd.	
Magnum Estates Limited	
Magnum Export	
Magnum Sea Foods Limited	
Malabar Arabian Fisheries	
Malnad Exports Pvt. Ltd.	
Mangala Marine Exim India Pvt. Ltd.	
Mangala Sea Products	
Mangala Seafoods	
Meenaxi Fisheries Pvt. Ltd.	
Milesh Marine Exports Private Limited	
MSRDR Exports	
MTR Foods	
Munnangi Sea Foods Pvt. Ltd.	
N.C. John & Sons (P) Ltd.	
Naga Hanuman Fish Packers	
Naik Frozen Foods Private Limited	
Naik Seafoods Ltd.	
Navayuga Exports	
Neeli Aqua Private Limited	

	Period to be reviewed
Nekkanti Sea Foods Limited	
Nezami Rekha Sea Foods Private Limited	
NGR Aqua International	
Nila Sea Foods Exports	
Nila Sea Foods Pvt. Ltd.	
Nine Up Frozen Foods	
Nutrient Marine Foods Limited	
Oceanic Edibles International Limited	
Overseas Marine Export	
Paragon Sea Foods Pvt. Ltd.	
Paramount Seafoods	
Parayil Food Products Pvt. Ltd.	
Penver Products Pvt. Ltd.	
Pesca Marine Products Pvt. Ltd.	
Pijikay International Exports P Ltd.	
Pisces Seafood International	
Premier Exports International	
Premier Marine Foods	
Premier Seafoods Exim (P) Ltd.	
R V R Marine Products Limited	
Raa Systems Pvt. Ltd.	
Raju Exports	
Ram's Assorted Cold Storage Ltd.	
Raunaq Ice & Cold Storage	
Raysons Aquatics Pvt. Ltd.	
Razban Seafoods Ltd.	
RBT Exports	
RDR Exports	
RF Exports	
Riviera Exports Pvt. Ltd.	
Rohi Marine Private Ltd.	
S & S Seafoods	
S Chanchala Combines	
S.A. Exports	
S.J. Seafoods	
Safa Enterprises	
Sagar Foods	
Sagar Grandhi Exports Private Limited	
Sagar Samrat Seafoods	
Sagarvihar Fisheries Pvt. Ltd.	
Sai Marine Exports Pvt. Ltd.	
SAI Sea Foods	
Salvam Exports (P) Ltd.	
Sanchita Marine Products Private Limited	
Sandhya Aqua Exports	
Sandhya Aqua Exports Pvt. Ltd.	
Sandhya Marines Limited	
Santhi Fisheries & Exports Ltd.	
Sarveshwari Exports	
Sawant Food Products	
Sea Foods Private Limited	
Seagold Overseas Pvt. Ltd.	
Selvam Exports Private Limited	
Sharat Industries Ltd.	
Sharma Industries	
Shimpo Exports Pvt. Ltd.	
Shippers Exports	
Shiva Frozen Food Exports Pvt. Ltd.	
Shree Datt Aquaculture Farms Pvt. Ltd.	
Shroff Processed Food & Cold Storage P Ltd.	
Silver Seafood	
Sita Marine Exports	
Sowmya Agri Marine Exports	
Sprint Exports Pvt. Ltd.	
Sri Chandrakantha Marine Exports	
Sri Sakkthi Cold Storage	
Sri Satya Marine Exports	
Sri Venkata Padmavathi Marine Foods Pvt. Ltd.	
Srikanth International	
Star Agro Marine Exports Private Limited	
Star Organic Foods Incorporated	
Sterling Foods	
Sun-Bio Technology Ltd.	
Supran Exim Private Limited	

	Period to be reviewed
Suryamitra Exim Pvt. Ltd.	
Suvarna Rekha Exports Private Limited	
Suvarna Rekha Marines P Ltd.	
TBR Exports Pvt Ltd.	
Teekay Marine P. Ltd.	
Tejaswani Enterprises	
The Waterbase Ltd.	
Triveni Fisheries P Ltd.	
Uniroyal Marine Exports Ltd.	
Unitriveni Overseas	
V V Marine Products	
V.S Exim Pvt Ltd.	
Vasista Marine	
Veejay Impex	
Veronica Marine Exports Private Limited	
Victoria Marine & Agro Exports Ltd.	
Vinner Marine	
Vishal Exports	
Vitality Aquaculture Pvt., Ltd.	
Wellcome Fisheries Limited	
West Coast Frozen Foods Private Limited	
Z A Sea Foods Pvt. Ltd.	
Thailand: Certain Frozen Warmwater Shrimp, A–549–822	2/1/14–1/31/15
A Foods 1991 Co., Limited/May Ao Foods Co., Ltd.[10]*	
A. Wattanachai Frozen Products Co., Ltd.*	
A.P. Frozen Foods Co., Ltd.*	
A.S. Intermarine Foods Co., Ltd.	
ACU Transport Co., Ltd.	
Ampai Frozen Foods Co., Ltd.	
Anglo-Siam Seafoods Co., Ltd.	
Apex Maritime (Thailand) Co., Ltd.	
Apitoon Enterprise Industry Co., Ltd.	
Applied DB Ind.	
Asian Seafood Coldstorage (Sriracha)*	
Asian Seafoods Coldstorage Public Co., Ltd./Asian Seafoods Coldstorage (Suratthani) Co., Limited/STC Foodpak Ltd.*[11]	
Assoc. Commercial Systems	
B.S.A. Food Products Co., Ltd.*	
Bangkok Dehydrated Marine Product Co., Ltd.*	
C Y Frozen Food Co., Ltd.	
C.P. Mdse	
C.P. Merchandising Co., Ltd.*	
CP Retailing and Marketing Co., Ltd.*	
C.P. Intertrade Co. Ltd.*	
Calsonic Kansei (Thailand) Co., Ltd.	
Century Industries Co., Ltd.	
Chaivaree Marine Products Co., Ltd.	
Chaiwarut Company Limited	
Charoen Pokphand Foods Public Co., Ltd.*	
Charoen Pokphand Petrochemical Co., Ltd.*	
Chonburi LC	
Chue Eie Mong Eak	
Commonwealth Trading Co., Ltd.	
Core Seafood Processing Co., Ltd.	
CPF Food Products Co., Ltd.*	
Crystal Frozen Foods Co., Ltd. and/or Crystal Seafood*	
Daedong (Thailand) Co. Ltd.	
Daiei Taigen (Thailand) Co., Ltd.	
Daiho (Thailand) Co., Ltd.	
Dynamic Intertransport Co., Ltd.	
Earth Food Manufacturing Co., Ltd.*	
F.A.I.T. Corporation Limited	
Far East Cold Storage Co., Ltd.	
Fimex VN	
Findus (Thailand) Ltd.	
Fortune Frozen Foods (Thailand) Co., Ltd.*	
Frozen Marine Products Co., Ltd.	
Gallant Ocean (Thailand) Co., Ltd.*	
Gallant Seafoods Corporation	
Global Maharaja Co., Ltd.	
Golden Sea Frozen Foods Co., Ltd.*	
Golden Thai Imp. & Exp. Co., Ltd.	
Good Fortune Cold Storage Co. Ltd.*	
Good Luck Product Co., Ltd.*	

	Period to be reviewed
Grobest Frozen Foods Co., Ltd.	
Gulf Coast Crab Intl.	
H.A.M. International Co., Ltd.	
Haitai Seafood Co., Ltd.	
Handy International (Thailand) Co., Ltd.*	
Heng Seafood Limited Partnership	
Heritrade	
HIC (Thailand) Co., Ltd.	
High Way International Co., Ltd.	
I.S.A. Value Co., Ltd.*	
I.T. Foods Industries Co., Ltd.*	
Inter-Oceanic Resources Co., Ltd.*	
Inter-Pacific Marine Products Co., Ltd.*	
K & U Enterprise Co., Ltd.*	
K Fresh	
K.D. Trading Co., Ltd.	
K.L. Cold Storage Co., Ltd.	
KF Foods Ltd.*	
Kiang Huat Sea Gull Trading Frozen Food Public Co., Ltd.*	
Kibun Trdg.	
Kingfisher Holdings Ltd.*	
Kitchens of the Oceans (Thailand) Company, Ltd.*	
Klang Co., Ltd.	
Kongphop Frozen Foods Co., Ltd.*	
Lee Heng Seafood Co., Ltd.*	
Leo Transports	
Li-Thai Frozen Foods Co., Ltd.	
Lucky Union Foods Co., Ltd.*	
Magnate & Syndicate Co., Ltd.	
Mahachai Food Processing Co., Ltd.	
Mahachai Marine Foods Co., Ltd.	
Marine Gold Products Ltd.[12]	
Merit Asia Foodstuff Co., Ltd.	
Merkur Co., Ltd.	
Ming Chao Ind Thailand	
N&N Foods Co., Ltd.	
N.R. Instant Produce Co., Ltd.*	
Namprik Maesri Ltd. Part.*	
Narong Seafood Co., Ltd.*	
Nongmon SMJ Products	
Ongkorn Cold Storage Co., Ltd./Thai-Ger Marine Co., Ltd.*	
Pacific Queen Co., Ltd.	
Pakfood Public Company Limited/Asia Pacific (Thailand) Co., Ltd./Chaophraya Cold Storage Co., Ltd./Okeanos Co., Ltd./Okeanos Food Co., Ltd./Takzin Samut Co., Ltd./Thai Union Frozen Products Public Co., Ltd./Thai Union Seafood Co., Ltd.[13]*	
Pakpanang Coldstorage Public Co., Ltd.*	
Penta Impex Co., Ltd.	
Pinwood Nineteen Ninety Nine	
Piti Seafood Co., Ltd.*	
Premier Frozen Products Co., Ltd.	
Preserved Food Specialty Co., Ltd.*	
Queen Marine Food Co., Ltd.	
Rayong Coldstorage (1987) Co., Ltd.	
S&D Marine Products Co., Ltd.*	
S&P Aquarium	
S&P Syndicate Public Company Ltd.	
S. Chaivaree Cold Storage Co., Ltd.	
S. Khonkaen Food Industry Public Co., Ltd. and/or S. Khonkaen Food Ind. Public*	
S.K. Foods (Thailand) Public Co. Limited*	
Samui Foods Company Limited	
Saota Seafood Factory	
SB Inter Food Co., Ltd.	
SCT Co., Ltd.	
Sea Bonanza Food Co., Ltd.	
SEA NT'L CO., LTD.	
Seafoods Enterprise Co., Ltd.	
Seafresh Fisheries/Seafresh Industry Public Co., Ltd.*	
Search and Serve	
Sethachon Co., Ltd.*	
Shianlin Bangkok Co., Ltd.	
Shing Fu Seaproducts Development Co.*	
Siam Food Supply Co., Ltd.	
Siam Haitian Frozen Food Co., Ltd.*	
Siam Intersea Co., Ltd.*	

	Period to be reviewed
Siam Marine Products Co. Ltd.	
Siam Ocean Frozen Foods Co. Ltd.*	
Siamchai International Food Co., Ltd.	
Smile Heart Foods Co. Ltd.*	
SMP Food Products, Co., Ltd.*	
Southport Seafood Co., Ltd.*	
Star Frozen Foods Co., Ltd.	
Starfoods Industries Co., Ltd.*	
Suntechthai Intertrading Co., Ltd.	
Surapon Foods Public Co., Ltd./Surat Seafoods Public Co., Ltd.*	
Surapon Nichirei Foods Co., Ltd.*	
Suratthani Marine Products Co., Ltd.*	
Suree Interfoods Co., Ltd.	
T.S.F. Seafood Co., Ltd.	
Tep Kinsho Foods Co., Ltd.*	
Teppitak Seafood Co., Ltd.	
Tey Seng Cold Storage Co., Ltd.*	
Thai Agri Foods Public Co., Ltd.	
Thai Hanjin Logistics Co., Ltd.	
Thai Mahachai Seafood Products Co., Ltd.*	
Thai Ocean Venture Co., Ltd.	
Thai Patana Frozen	
Thai Prawn Culture Center Co., Ltd.	
Thai Royal Frozen Food Co., Ltd.*	
Thai Spring Fish Co., Ltd.*	
Thai Union Manufacturing Company Limited*	
Thai World Imports and Exports Co., Ltd.	
Thai Yoo Ltd., Part.	
The Siam Union Frozen Foods Co., Ltd.*	
The Union Frozen Products Co., Ltd./Bright Sea Co., Ltd.*	
Trang Seafood Products Public Co., Ltd.	
Transamut Food Co., Ltd.*	
Tung Lieng Tradg	
United Cold Storage Co., Ltd.	
UTXI Aquatic Products Processing Company	
V. Thai Food Product Co., Ltd.*	
Wann Fisheries Co., Ltd.*	
Xian-Ning Seafood Co., Ltd.*	
Yeenin Frozen Foods Co., Ltd.*	
YHS Singapore Pte	
ZAFCO TRDG	

[7] On December 11, 2012, the Department determined that Apex Frozen Foods Private Limited is the successor-in-interest to Apex Exports. *See Final Results of Antidumping Duty Changed Circumstances Review: Certain Frozen Warmwater Shrimp From India,* 77 FR 73619 (December 11, 2012).

[8] On December 2, 2014, Premier Marine Products Private Limited was found to be the successor-in-interest to Premier Marine Products. *See Notice of Final Results of Antidumping Duty Changed Circumstances Review: Certain Frozen Warmwater Shrimp from India,* 79 FR 71384 (December 2, 2014).

[9] Shrimp produced and exported by Devi Sea Foods (Devi) was excluded from the AD Indian order effective February 1, 2009. *See Certain Frozen Warmwater Shrimp From India: Final Results of Antidumping Duty Administrative Review, Partial Rescission of Review, and Notice of Revocation of Order in Part,* 75 FR 41813, 41814 (July 19, 2010). Accordingly, we are initiating this administrative review with respect to Devi only for shrimp produced in India where Devi acted as either the manufacturer or exporter (but not both).

[10] On December 1, 2010, the Department found that A Foods 1991 Co., Limited is the successor-in-interest to May Ao Company Limited. *See Notice of Final Results of Antidumping Duty Changed Circumstances Review: Certain Frozen Warmwater Shrimp from Thailand,* 75 FR 74684 (Dec. 1, 2010). Because the effective date of this determination is during a prior POR, we included only A Foods 1991 Co., Limited for purposes of initiation.

[11] The request for deferral only covered Asian Seafoods Coldstorage Public Co., Ltd. and Asian Seafoods Coldstorage (Suratthani) Co., Limited.

[12] Shrimp produced and exported by Marine Gold Products Ltd. (Marine Gold) were excluded from the AD Thailand order effective February 1, 2012. *See 2011–2012 Thai Shrimp,* 78 FR at 42499. Accordingly, we are initiating this administrative review with respect to Marine Gold only for shrimp produced in Thailand where Marine Gold acted as either the manufacturer or exporter (but not both).

[13] In the 2012–2013 administrative review, the Department found that the following companies comprised a single entity: Thai Union Frozen Products Public Co. Ltd. and its affiliates, and Pakfood Public Company Limited and its affiliates. *See 2012–2013 Thai Shrimp,* 79 FR 51306. Absent information to the contrary, we intend to continue to treat these companies as a single entity for purposes of this administrative review.

Administrative Protective Orders and Letters of Appearance

Interested parties must submit applications for disclosure under administrative protective orders in accordance with 19 CFR 351.305. On January 22, 2008, the Department published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Those procedures apply to the administrative reviews included in this notice of initiation. Parties wishing to participate in either of these administrative reviews should ensure that they meet the requirements of these procedures (*e.g.,* the filing of separate letters of appearance as discussed at 19 CFR 351.103(d)).

Revised Factual Information 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) other data or statements of facts; (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. Please review the final rule, available at *http://enforcement.trade.gov/frn/2013/1304frn/2013-08227.txt,* prior to submitting factual information in these segments.

Any party submitting factual information in an antidumping duty proceeding must certify to the accuracy and completeness of that information.[14] Parties are hereby reminded that revised certification requirements are in effect for company/government officials as well as their representatives. All segments of any antidumping duty proceedings initiated on or after August 16, 2013, should use the formats for the revised certifications provided at the end of the *Final Rule.*[15] The Department intends to reject factual submissions in these administrative reviews if the submitting party does not comply with applicable revised certification requirements.

Revised Extension of Time Limits Regulation

On September 20, 2013, the Department modified its regulation concerning the extension of time limits for submissions in antidumping duty proceedings.[16] The modification clarifies that parties may request an extension of time limits before a time limit established under Part 351 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. Examples include, but are not limited to: (1) Case and rebuttal briefs, filed pursuant to 19 CFR 351.309; (2) submissions containing rebuttal, clarification and correction filed pursuant to 19 CFR 351.301(c)(3)(iv); (3) comments concerning CBP data; and (4) quantity and value questionnaire responses. 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. Please 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 administrative reviews.

These initiations and this notice are in accordance with section 751(a) of the Act (19 U.S.C. 1675(a)) and 19 CFR 351.221(c)(1)(i).

Dated: March 24, 2015.

Gary Taverman

Associate Deputy Assistant Secretary, for Antidumping and Countervailing Duty Operations.

[FR Doc. 2015–07197 Filed 3–27–15; 8:45 am]

BILLING CODE 3510–DS–P

[14] *See* section 782(b) of the Act.

[15] *See Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*); *see also* the frequently asked questions regarding the *Final Rule,* available at: *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

[16] *See Extension of Time Limits: Final Rule,* 78 FR 57790 (September 20, 2013).

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: Deep Seabed Mining Exploration Licenses.

OMB Control Number: 0648–0145.

Form Number(s): None.

Type of Request: Regular (extension of a currently approved information collection).

Number of Respondents: 1.

Average Hours per Response: License renewals, 200 (annualized over 5 years to 40 hours); annual reports, 20 hours.

Burden Hours: 60.

Needs and Uses: This request is for extension of a currently approved information collection.

NOAA's regulations at 15 CFR part 970 govern the issuing and monitoring of exploration licenses under the Deep Seabed Hard Mineral Resources Act. Any persons seeking a license must submit certain information that allows NOAA to ensure the applicant meets the standards of the Act. Persons with licenses are required to conduct monitoring and make reports, and they may request revisions, transfers, or extensions of licenses.

Affected Public: Business or other for-profit organizations.

Frequency: Annually and every five years.

Respondent's Obligation: Required to obtain or maintain benefits.

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: March 24, 2015.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2015–07149 Filed 3–27–15; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD836

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 41 pre Data Workshop II webinar.

SUMMARY: The SEDAR 41 assessments of the South Atlantic stocks of red snapper and gray triggerfish will consist of a series of workshops and webinars: Data Workshops; an Assessment Process; and a Review Workshop. This notice is for a webinar associated with the Data portion of the SEDAR process. See **SUPPLEMENTARY INFORMATION.**

DATES: A SEDAR 41 pre Data Workshop II webinar will be held on Wednesday, April 15, 2015 from 1 p.m. until 5 p.m. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from, or completed prior to the time established by this notice.

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julia Byrd at SEDAR (see **FOR FURTHER INFORMATION CONTACT** below) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julia Byrd, SEDAR Coordinator; telephone: (843) 571–4366; email: *julia.byrd@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three-step process including: (1) Data Workshop(s); (2) Assessment Process; and (3) Review Workshop. The product of the Data Workshop(s) is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: Data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion in the pre Data Workshop webinar are as follows:

1. Participants will review decisions made at the 2014 data workshop.
2. Identify topics for discussion at the 2015 data workshop.
3. Identify individuals responsible for updating and/or providing new datasets.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the SEDAR office (see **ADDRESSES**) at least 10 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: March 25, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–07174 Filed 3–27–15; 8:45 am]

BILLING CODE 3510–22–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities Under OMB Review

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (PRA), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected costs and burden.

DATES: Comments must be submitted on or before April 29, 2015.

ADDRESSES: Comments regarding the burden estimated or any other aspect of the information collection, including suggestions for reducing the burden, may be submitted directly to OMB within 30 days of the notice's publication by email at *OIRAsubmissions@omb.eop.gov.* Please identify the comments by OMB Control No. 3038–0076. Please provide the Commission with a copy of all submitted comments at the address listed below. Please refer to OMB Reference No. 3038–0076, found on *http://reginfo.gov.* Comments may also be mailed to the Office of Information

and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Commodity Futures Trading Commission, 725 17th Street NW., Washington, DC 20503, and to Eileen Chotiner, Senior Program Analyst, Division of Clearing and Risk, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581. Comments may also be submitted by any of the following methods:

- *Agency Web site, via its Comments Online process: http://comments.cftc.gov.* Follow the instructions for submitting comments through the Web site.
- *Mail:* Send to Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail, above.
- *Federal eRulemaking Portal: http://www.regulations.gov/.* Follow the instructions for submitting comments.

Please submit your comments to the Commission using only one of these methods.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures set forth in section 145.9 of the Commission's regulations.[1]

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the rulemaking will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: Eileen Chotiner, Division of Clearing and Risk, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581; (202) 418–5467; email: *echotiner@cftc.gov,* and refer to OMB Control No. 3038–0076.

SUPPLEMENTARY INFORMATION:

Title: ''Risk Management Requirements for Derivatives Clearing Organizations, 3038–0076.'' This is a request for extension of a currently approved information collection.

Abstract: Part 39 of the Commission's regulations establishes risk management requirements for derivatives clearing organizations (''DCOs''), which are required to be registered with the Commission. Part 39 also establishes procedures for registration of DCOs. The Commission will use the information in this collection to assess compliance of DCOs and DCO applicants with requirements for DCOs prescribed in the Commodity Exchange Act and Commission regulations.

Burden Statement: The respondent burden for this collection is estimated to average 10 hours per response.

Respondents/Affected Entities: Derivatives clearing organizations and applicants for registration as a derivatives clearing organization.

Estimated Number of Respondents: 17.

Estimated Total Annual Burden on Respondents: 1,903 hours.

Frequency of Collection: On occasion.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: March 25, 2015.

Christopher J. Kirkpatrick,

Secretary of the Commission.

[FR Doc. 2015–07201 Filed 3–27–15; 8:45 am]

BILLING CODE 6351–01–P

[1] Commission regulations referred to herein are found at 17 CFR 1 *et seq.* (2014).

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2015–OS–0007]

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by April 29, 2015.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493.

SUPPLEMENTARY INFORMATION:

Title, Associated Form and OMB Number: Certification of Qualified Products; DD Form 1718; OMB Control Number 0704–0487.

Type of Request: Extension.

Number of Respondents: 1,276.

Responses per Respondent: 1.

Annual Responses: 1,276.

Average Burden per Response: 30 minutes.

Annual Burden Hours: 638.

Needs and Uses: The information collection requirement is necessary to obtain, certify and record qualification of products or processes falling under the DoD Qualification Program. This form is included as an exhibit in an appeal or hearing case file as evidence of the reviewer's products or process qualifications in advance of, and independent of an acquisition.

Affected Public: Business or other for profit.

Frequency: Biennially.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Jasmeet Seehra.

Written comments and recommendations on the proposed information collection should be sent to Ms. Jasmeet Seehra at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

You may also submit comments, identified by docket number and title, by the following method:

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

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Written requests for copies of the information collection proposal should be sent to Mr. Licari at WHS/ESD Directives Division, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Dated: March 25, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015–07191 Filed 3–27–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2015–OS–0027]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary for Personnel and Readiness, DoD.

ACTION: Notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. 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 information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by May 29, 2015.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Mail: Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the OUSD (Personnel and Readiness) Office of Total Force Planning & Requirements, ATTN: Mr. Thomas Hessel, 4000 Pentagon, Washington, DC 20301, or call 703–697–3402.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Department of Defense Inventory of Contracts for Services Compliance; OMB Control Number 0704–0491.

Needs and Uses: The information collection requirement is necessary to allow all DoD organizations to fully implement sections 235 and 2330a of title 10, United States Code.

The information requested, such as the Reporting Period, Contract number, Task/Delivery Order Number, Customer Name and Address, Contracting Office Name and Address, Federal Supply Class or Service Code, Contractor Name and Address, Value of Contract Instrument, and the Number and Value of Direct Labor Hours will be used to facilitate the accurate identification of the function performed and to facilitate the estimate of the reliability of the data. The Direct Labor Hours are requested for use in calculating contractor manpower equivalents. This information is reported directly from the contractor because this is the most credible data source.

Affected Public: Business or other for profit; not-for-profit institutions.

Annual Burden Hours: 4,074.

Number of Respondents: 48,884.

Responses per Respondent: 1.

Average Burden Per Response: 5 minutes.

Frequency: Annually.

Respondent's obligation: Required to obtain or retain benefits.

Dated: March 25, 2015.

Aaron Siegel,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2015–07193 Filed 3–27–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Privacy Act of 1974; System of Records; Impact Evaluation of Training in Multi-Tiered Systems of Support for Behavior

AGENCY: Institute of Education Sciences, Department of Education.

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended (Privacy Act), the Department of Education (Department) publishes this notice of a new system of records entitled ''Impact Evaluation of Training in Multi-Tiered Systems of Support for Behavior'' (18–13–38). The National Center for Education Evaluation and Regional Assistance at the Department's Institute of Education Sciences (IES) awarded a contract in November 2013 to MDRC to provide evidence on the effectiveness of training teachers and school staff in multi-tiered systems of supports for behavior (MTSS–B).

DATES: Submit your comments on this proposed new system of records on or before April 29, 2015.

The Department filed a report describing the new system of records covered by this notice with the Chair of the Senate Committee on Homeland Security and Governmental Affairs, the Chair of the House Committee on Oversight and Government Reform, and the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on March 18, 2015. This system of records will become effective on the later date of: (1) The expiration of the 40-day period for OMB review on April 27, 2015, unless OMB waives 10 days of the 40-day review period for compelling reasons shown by the Department, or (2) April 29, 2015, unless the system of records needs to be changed as a result of public comment or OMB review. The Department will publish any changes to the system of records or routine uses that result from public comment or OMB review.

ADDRESSES: Address all comments about the new system of records to Dr. Audrey Pendleton, Associate Commissioner, Evaluation Division, National Center for Education Evaluation and Regional Assistance, Institute of Education Sciences, U.S. Department of Education, 555 New Jersey Avenue NW., Room 502D, Washington, DC 20208–0001. Telephone: (202) 208–7078. If you prefer to send your comments via email, use the following address: *comments@ed.gov.*

You must include the phrase ''Impact Evaluation of Training in Multi-Tiered Systems of Support for Behavior'' in the subject line of the email.

During and after the comment period, you may inspect all public comments about this notice at the Department in Room 502D, 555 New Jersey Avenue NW., Washington, DC, between the hours of 8:00 a.m. and 4:30 p.m., Washington, DC time, Monday through

Friday of each week except Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record

On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Dr. Audrey Pendleton, Associate Commissioner, Evaluation Division, National Center for Education Evaluation and Regional Assistance, Institute of Education Sciences, U.S. Department of Education, 555 New Jersey Avenue NW., Room 502D, Washington, DC 20208–0001. Telephone: (202) 208–7078. If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), you may call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities can obtain this document in an accessible format (*e.g.*, braille, large print, audiotape, or compact disc) on request to the contact person listed in this section.

SUPPLEMENTARY INFORMATION:

Introduction

The Privacy Act (5 U.S.C. 552a (e)(4) and (e)(11)) requires the Department to publish in the **Federal Register** this notice of a new system of records maintained by the Department. The Department's regulations implementing the Privacy Act are contained in part 5b of title 34 of the Code of Federal Regulations (CFR).

The Privacy Act applies to any record about an individual that is maintained in a system of records from which individually identifying information is retrieved by a unique identifier associated with each individual, such as a name or Social Security number (SSN). The information about each individual is called a ''record,'' and the system, whether manual or computer-based, is called a ''system of records.''

The Privacy Act requires each agency to publish a notice of a system of records in the **Federal Register** and to prepare and send a report to OMB whenever the agency publishes a new system of records or makes a significant change to an established system of records. Each agency is also required to send copies of the report to the Chair of the Senate Committee on Homeland Security and Governmental Affairs and the Chair of the House Committee on Oversight and Government Reform. These reports are intended to permit an evaluation of the probable effect of the proposal on the privacy rights of individuals.

The system will contain personally identifying information on approximately 38,000 students and 3,600 teachers and other school staff from 12 school districts and will include, but not necessarily be limited to, data on: (1) For students, standardized math and English/Language Arts test scores, age, sex, race/ethnicity, grade, eligibility for free/reduced-price lunches, English Learner status, individualized education program status, school enrollment dates, attendance, discipline records, school engagement, and student behavior, and (2) for teachers and other school staff, school assignments, positions, grades and subjects taught, any available teacher and staff background characteristics, including age, sex, race/ethnicity, certifications, and years of teaching experience, and classroom management and behavior support practices.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov*. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: March 19, 2015.

Sue Betka,

Acting Director, Institute of Education Sciences.

For the reasons discussed in the preamble, the Director of the Institute of Education Sciences, U.S. Department of Education (Department) publishes a notice of a new system of records to read as follows:

SYSTEM NUMBER:

18–13–38

SYSTEM NAME:

Impact Evaluation of Training in Multi-Tiered Systems of Support for Behavior.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATIONS:

(1) Evaluation Division, National Center for Education Evaluation and Regional Assistance, Institute of Education Sciences (IES), U.S. Department of Education, 555 New Jersey Avenue NW., Room 502D, Washington, DC 20208–0001.

(2) MDRC, 16 East 34 Street, 19th Floor, New York, NY 10016–4326 (contractor).

(3) American Institutes for Research (AIR), 1000 Thomas Jefferson Street NW., Washington, DC 20007–3835 (subcontractor).

(4) Decision Information Resources (DIR), Inc., 2600 Southwest Freeway, Suite 900, Houston, TX 77098–4610 (subcontractor).

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system of records will include personally identifying information about the students as well as teachers and other school staff who participate in the study. The system will contain records on approximately 38,000 students and 3,600 teachers and other school staff from 12 school districts.

CATEGORIES OF RECORDS IN THE SYSTEM:

For students, this information will include, but will not necessarily be limited to, standardized math and English/Language Arts test scores, age, sex, race/ethnicity, grade, eligibility for free/reduced-price lunches, English Learner status, individualized education program status, school enrollment dates, attendance, discipline records, school engagement, and student behavior. For teachers and other school staff, this information will include, but will not necessarily be limited to, school assignments, positions, grades and subjects taught, any available teacher and staff background characteristics, including age, sex, race/ethnicity, certifications, and years of teaching experience, and classroom management and behavior support practices.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The system of records is authorized under sections 171(b) and 173 of the Education Sciences Reform Act of 2002 (ESRA) (20 U.S.C. 9561(b) and 9563) and section 664 of the Individuals with Disabilities Education Improvement Act of 2004 (20 U.S.C. 1464).

PURPOSE(S):

The information contained in the records maintained in this system will be used to conduct a rigorous study of the effectiveness of providing school staff with training in multi-tiered systems of supports for behavior.

The study will address the following central research questions: What are the impacts on school climate, school staff practice, and student outcomes of providing training in MTSS–B that includes universal supports (Tier I)? What are the impacts on school climate, school staff practice, and student outcomes of providing training in MTSS–B that includes universal supports (Tier I) plus targeted interventions for at-risk students (Tier II)? What is the impact of additional training in targeted interventions for at-risk students (Tier II) for schools already trained in MTSS–B that includes universal supports (Tier I)? What are the impacts for relevant subgroups including students with at-risk behavior, students with disabilities, and teachers with less experience? Which strategies are correlated with improvement in student outcomes?

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The Department may disclose information contained in a record in this system of records under the routine uses listed in this system of records without the consent of the individual if the disclosure is compatible with the purposes for which the record was collected. The Department may make these disclosures on a case-by-case basis or, if the Department has complied with the computer matching requirements of the Privacy Act of 1974, as amended (Privacy Act), under a computer matching agreement. Any disclosure of individually identifiable information from a record in this system must also comply with the requirements of section 183 of the ESRA (20 U.S.C. 9573) providing for confidentiality standards that apply to all collection, reporting, and publication of data by the Institute of Education Sciences. It must also comply with the requirements of the Family Educational Rights and Privacy Act (20 U.S.C. 1232g; 34 CFR part 99), which protects the privacy of student education records.

The Department may disclose records under the ''contract disclosure'' proposed routine use. If the Department contracts with an entity for the purpose of performing any function that requires disclosure of records in this system to employees of the contractor, the Department may disclose the records to those employees who have received the appropriate level of security clearance from the Department. Before entering into such a contract, the Department will require the contractor to maintain Privacy Act safeguards, as required under 5 U.S.C. 552a(m), with respect to the records in the system.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

The Department will maintain records on CD–ROM, and the contractor (MDRC) and subcontractors (AIR and DIR) will maintain data for this system on computers and in hard copy.

RETRIEVABILITY:

Records in this system will be indexed and retrieved by a unique number assigned to each individual that is cross-referenced by the individual's name on a separate list.

SAFEGUARDS:

All physical access to the Department's site and to the sites of the Department's contractor and subcontractors, where this system of records will be maintained, is controlled and monitored by security personnel. The computer system employed by the Department offers a high degree of resistance to tampering and circumvention. This security system limits data access to Department and contract staff on a need-to-know basis and controls individual users' ability to access and alter records within the system.

The contractor and subcontractors will establish a similar set of procedures at their sites to ensure confidentiality of data. The contractor and subcontractors are required to ensure that information identifying individuals is in files physically separated from other research data and electronic files identifying individuals are separated from other electronic research data files. The contractor will maintain security of the complete set of all master data files and documentation. Access to individually identifiable data will be strictly controlled. All information will be kept in locked file cabinets during nonworking hours, and work on hardcopy data will take place in a single room, except for data entry.

Physical security of electronic data also will be maintained. Security features that protect project data will include: Password-protected accounts that authorize users to use the contractor's system but to access only specific network directories and network software; user rights and directory and file attributes that limit those who can use particular directories and files and determine how they can use them; and additional security features that the network administrators will establish for projects as needed. The Department's, the contractor's, and the subcontractor's employees who ''maintain'' (collect, maintain, use, or disseminate) data in this system must comply with the requirements of the Privacy Act and the confidentiality standards in section 183 of the ESRA (20 U.S.C. 9573).

RETENTION AND DISPOSAL:

Records are maintained and disposed of in accordance with the Department's Records Disposition Schedules (GRS 23, Item 8).

SYSTEM MANAGER AND ADDRESS:

Associate Commissioner, Evaluation Division, National Center for Education Evaluation and Regional Assistance, Institute of Education Sciences, U.S. Department of Education, 555 New Jersey Avenue NW., Room 502D, Washington, DC 20208–0001.

NOTIFICATION PROCEDURE:

If you wish to determine whether a record exists regarding you in the system of records, contact the system manager. Your request must meet the requirements of the Department's Privacy Act regulations at 34 CFR 5b.5, including proof of identity.

RECORD ACCESS PROCEDURE:

If you wish to gain access to a record about you in this system of records, contact the system manager. Your request must meet the requirements of the Department's Privacy Act regulations at 34 CFR 5b.5, including proof of identity.

CONTESTING RECORD PROCEDURE:

If you wish to contest the content of a record regarding you in the system of records, contact the system manager. Your request must meet the requirements of the Department's Privacy Act regulations at 34 CFR 5b.7, including proof of identity.

RECORD SOURCE CATEGORIES:

This system will contain records on students as well as teachers and other school staff in an impact evaluation of training in multi-tiered systems of supports for behavior. Data will be obtained through human resource and student administrative records maintained by the school districts,

surveys of students as well as teachers and other school staff, observations of classrooms, ratings of student behavior, and individual student testing.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 2015–07321 Filed 3–27–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2015–ICCD–0036]

Agency Information Collection Activities; Comment Request; Study on Sustaining the Positive Effects of Preschool

AGENCY: Office of Planning Evaluation and Policy Development (OPEPD), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), ED is proposing new information collection.

DATES: Interested persons are invited to submit comments on or before May 29, 2015.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2015–ICCD–0036 or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will ONLY accept comments during the comment period in this mailbox when the regulations.gov site is not available.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Mailstop L–OM–2–2E319, Room 2E103, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Erica Lee, (202) 260–1463.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Study on Sustaining the Positive Effects of Preschool.

OMB Control Number: 1875–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: State, Local and Tribal Governments.

Total Estimated Number of Annual Responses: 28.

Total Estimated Number of Annual Burden Hours: 28.

Abstract: Policy and Program Studies Service, with OPEPD, contracted with the American Institutes for Research (AIR) to conduct five case studies of programs that are designed to sustain the positive effects of preschools. On-site case studies will include interviews with district officials, principals, Kindergarten teachers, preschool teachers, program funders, and program evaluators.

Dated: March 24, 2015.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2015–07103 Filed 3–27–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Investing in Innovation Fund—Development Grants

AGENCY: Office of Innovation and Improvement, Department of Education.

ACTION: Notice.

Overview Information

Investing in Innovation Fund—Development grants Notice inviting applications for new awards for fiscal year (FY) 2015.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.411P (Development grants Pre-Application) and 84.411C (Development grants Full Application).

Note: In order to receive an Investing in Innovation Fund (i3) Development grant, an entity must submit a pre-application. The pre-application is intended to reduce the burden of submitting a full application for an i3 Development grant. Pre-applications will be reviewed and scored by peer reviewers using the selection criteria designated in this notice. Entities that submit a highly rated pre-application will be invited to submit a full application for a Development grant; however, any entity that successfully submits a pre-application may choose to submit a full application.

DATES: *Pre-Applications Available:* April 1, 2015.

Deadline for Notice of Intent To Submit Pre-Application: April 20, 2015.

Deadline for Transmittal of Pre-applications: April 29, 2015.

Full Applications Available: If you are invited to submit a full application for a Development grant, we will transmit the full application package and instructions using the contact information you provide to us in your pre-application. Other pre-applicants who choose to submit a full application may access these items on the i3 Web site at *www2.ed.gov/programs/innovation/index.html.*

Deadline for Transmittal of Full Applications: Entities that submit a highly rated pre-application, as scored by peer reviewers and as identified by the Department, will be invited to submit a full application for a Development grant. Other pre-applicants may choose to submit a full application. The Department will announce on its Web site the deadline date for transmission of full applications and will also communicate this deadline to applicants in the full application package and instructions.

Deadline for Intergovernmental Review: 60 calendar days after the deadline date for transmittal of full applications.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The Investing in Innovation Fund (i3), established under section 14007 of the American Recovery and Reinvestment Act of 2009 (ARRA), provides funding to support (1) local educational agencies (LEAs), and (2) nonprofit organizations in partnership with (a) one or more LEAs or (b) a consortium of schools. The i3 program is designed to generate and validate solutions to persistent educational challenges and to support the expansion of effective solutions to serve substantially larger numbers of students. The central design element of the i3 program is its multi-tier structure that links the amount of funding that an applicant may receive to the quality of the evidence supporting the efficacy of the proposed project. Applicants proposing practices supported by limited evidence can receive relatively small grants that support the development and initial evaluation of promising practices and help to identify new solutions to pressing challenges; applicants proposing practices supported by evidence from rigorous evaluations, such as large randomized controlled trials, can receive sizable grants to support expansion across the country. This structure provides incentives for applicants to build evidence of effectiveness of their proposed projects and to address the barriers to serving more students across schools, districts, and States.

As importantly, all i3 projects are required to generate additional evidence of effectiveness. All i3 grantees must use part of their budgets to conduct independent evaluations (as defined in this notice) of their projects. This ensures that projects funded under the i3 program contribute significantly to improving the information available to practitioners and policymakers about which practices work, for which types of students, and in what contexts.

The Department awards three types of grants under this program: ''Development'' grants, ''Validation'' grants, and ''Scale-Up'' grants. These grants differ in terms of the level of prior evidence of effectiveness required for consideration of funding, the level of scale the funded project should reach, and, consequently, the amount of funding available to support the project. Development grants provide funding to support the development or testing of practices that are supported by evidence of promise (as defined in this notice) or a strong theory (as defined in this notice) and whose efficacy should be systematically studied. Development grants will support new or substantially more effective practices for addressing widely shared challenges. Development projects are novel and significant nationally, not projects that simply implement existing practices in additional locations or support needs that are primarily local in nature. All Development grantees must evaluate the effectiveness of the project at the level of scale proposed in the application. This notice invites applications for Development grants only. The Department anticipates publishing notices inviting applications for the other types of i3 grants (Validation and Scale-Up grants) in the spring of 2015.

We remind LEAs of the continuing applicability of the provisions of the Individuals with Disabilities Education Act (IDEA) for students who may be served under i3 grants. Any grants in which LEAs participate must be consistent with the rights, protections, and processes established under IDEA for students who are receiving special education and related services or are in the process of being evaluated to determine their eligibility for such services.

As described later in this notice, in connection with making competitive grant awards, an applicant is required, as a condition of receiving assistance under this program, to make civil rights assurances, including an assurance that its program or activity will comply with Section 504 of the Rehabilitation Act of 1973, as amended and the Department's section 504 implementing regulations, which prohibit discrimination on the basis of disability. Regardless of whether a student with disabilities is specifically targeted as a ''high-need student'' (as defined in this notice) in a particular grant application, recipients are required to comply with all legal nondiscrimination requirements, including, but not limited to the obligation to ensure that students with disabilities are not denied access to the benefits of the recipient's program because of their disability. The Department also enforces Title II of the Americans with Disabilities Act (ADA), as well as the regulations implementing Title II of the ADA, which prohibit discrimination on the basis of disability by public entities.

Furthermore, Title VI and Title IX of the Civil Rights Act of 1964 prohibit discrimination on the basis of race, color, and national origin, and sex, respectively. On December 2, 2011, the Departments of Education and Justice jointly issued guidance that explains how educational institutions can promote student diversity or avoid racial isolation within the framework of Title VI (*e.g.,* through consideration of the racial demographics of neighborhoods when drawing assignment zones for schools or through targeted recruiting efforts). The ''Guidance on the Voluntary Use of Race to Achieve Diversity and Avoid Racial Isolation in Elementary and Secondary Schools'' is available on the Department's Web site at *www.ed.gov/ocr/docs/guidance-ese-201111.pdf.*

Background: Through its competitions, the i3 program strives to improve the academic achievement of high-need students by accelerating the identification of promising solutions to pressing challenges in kindergarten through grade 12 (K–12) education, supporting the evaluation of the efficacy of such solutions, and developing new approaches to scaling effective practices to serve more students. The i3 program aims to build a portfolio of solutions and corresponding evidence regarding different approaches to addressing critical challenges in education. When selecting the priorities for a given competition, the Department considers several factors, including the Department's policy priorities, the need for new solutions in a particular priority area, the extent of the existing evidence in the field supporting effective practices in a particular priority area, whether other available funding exists for a particular priority area, and the results and lessons learned from funded projects from prior i3 competitions. We note that in previous i3 Development competitions, the Department has included explicit priority areas for supporting students with disabilities and English learners. Most of the projects in i3's current portfolio are supporting these students in some way. Our approach for the FY 2015 competition, as further described below, is to focus on projects that are designed to test new or otherwise promising approaches that may impact a broad spectrum of students, including students with disabilities and English learners. Although the FY 2015 i3 Development competition does not include specific priorities for supporting English learners or students with disabilities, we require applicants to serve high-need student populations, and we encourage them to consider ways in which their proposed projects could serve students with disabilities or English learners.

We include five absolute priorities in the FY 2015 Development competition. We include absolute priorities that are intended to represent persistent challenges in education, new areas of policy focus in which research is scarce, and areas we would like to strengthen

the current portfolio of i3 grantee projects. Applicants applying under the Serving Rural Communities priority (Absolute Priority 5) must also address one of the other four absolute priorities established for the FY 2015 i3 Development competition, as described below, while serving students enrolled in rural LEAs (as defined in this notice). We also include one competitive preference priority for novice i3 applicants.

First, we include an absolute priority that asks applicants to increase the number and percentage of highly effective principals. School leaders play an essential role in shaping school cultures, aligning parents and educators around shared goals, and, ultimately, influencing student achievement. Yet preparation programs and support for school leaders are often lacking. Preparation programs, for example, sometimes lack rigorous screening and selection entry requirements, offer courses that are not aligned with standards of practice, and provide insufficient clinical experiences for candidates. Furthermore, current principals indicate that they are not reliably provided the necessary support and development opportunities that enable them to shape a strong professional community and collective responsibility for student learning. We encourage applicants addressing this priority to consider strategies that improve hiring, support, and retention efforts for principals with the ultimate outcome of improving outcomes for high-need students (as defined in this notice). We think these areas are important to explore further, as the research base on effective practices for training, supporting, and retaining strong leaders is limited.

Second, we include an absolute priority on improving science, technology, engineering, and mathematics (STEM) education. Research shows that ensuring that all students can access and excel in STEM fields is essential to our Nation's economy and future prosperity.[1] Careers in STEM fields are growing, as are the skills required to compete for and succeed in these specialized jobs.[2] In addition, STEM literacy is beneficial even for those who are not directly involved in STEM professions. For this priority, we seek projects that reach students beyond the boundaries of the traditional school day (*e.g.,* during out-of-school time or extended-day programs) and provide meaningful, real-world STEM learning experiences that will inspire students' interest in STEM and give them the tools they need to meet the demands of dynamic labor markets.

Third, we include an absolute priority that supports the use of technology in the classroom to support student learning and inform teacher professional development. In this priority, we seek projects that use technological tools that enable the development, visualization, and rapid analysis of data to inform instructional practices and improve learning outcomes. Incorporating real-time data into instructional practice provides students with the individualized support they need to be successful and can also be leveraged to provide educators with targeted support that helps them meet students' needs. We seek projects that will examine the effectiveness of various approaches to providing student and teacher support and build the research base.

Fourth, we include an absolute priority on influencing the development of non-cognitive factors. Non-cognitive factors may encompass many skills and behaviors, including but not limited to academic behaviors, academic mindset, perseverance, self-regulation, social and emotional skills, and approaches toward learning strategies. A promising body of research suggests that non-cognitive factors play an important role in students' academic, career, and life outcomes.[3] Notably, some initial interventions focused on enhancing these skills and behaviors are seemingly scalable and lower-cost as compared to more conventional education interventions—and have a disproportionately positive impact on students most in need.[4] As interest in this area grows, we think it is important to identify solutions and build evidence to determine effective ways to help students develop such skills and behaviors (*e.g.,* interventions that directly target students, support changes in educators' instructional practices, or redesign learning environments), as well as how to measure such skills and behaviors in valid and reliable ways, and to demonstrate how improvement in such skills and behaviors affects overall student outcomes.

Fifth, we include an absolute priority that focuses on serving rural communities. Students living in rural communities face unique challenges. Applicants applying under this priority must also address one of the other four absolute priorities established for the FY 2015 i3 Development competition, as described above, while serving students enrolled in rural LEAs (as defined in this notice).

Finally, in order to expand the reach of the i3 program and encourage entities that have not previously received an i3 grant to apply, the Department includes a competitive preference priority for novice i3 applicants. A novice i3 applicant is an applicant that has never received a grant under the i3 program. An applicant must identify whether it is a novice applicant when completing the applicant information sheet. Instructions on how to complete the applicant information sheet are included in the application package.

In summary, applications must address one of the first four absolute priorities for this competition and propose projects designed to implement practices that serve students who are in grades K–12 at some point during the funding period. If an applicant chooses to also address the absolute priority regarding students in rural LEAs, that applicant must also address one of the other four absolute priorities established for the FY 2015 i3 Development competition, as described above, while serving students enrolled in rural LEAs (as defined in this notice). Applicants must be able to demonstrate that the proposed process, product, strategy, or practice included in their applications is supported by either evidence of promise (as defined in this notice) or a strong theory (as defined in this notice). Applicants should carefully review all of the requirements in the *Eligibility Information* section of this notice for instructions on how to demonstrate the proposed project is supported by evidence of promise (as defined in this notice) or a strong theory (as defined in

[1] Langdon, D.; McKittrick, G.; Beede, D.; Khan, B.; and Doms, M., Office of the Chief Economist, U.S. Department of Commerce. STEM: Good Jobs Now and for the Future (July 2011). *Available at: http://www.esa.doc.gov/sites/default/files/stemfinalyjuly14_1.pdf.*

[2] Chairman's Staff of the Joint Economic Committee. Calculations using data from the Bureau of Labor Statistics. Employment Projections: 2010–20. Table 1.7 Occupational Employment and Job Openings Data, Projected 2010–20, and Worker Characteristics, 2010. February 2012. *Available at: http://bls.gov/emp/.* For the purposes of this calculation, STEM occupations are defined as in the U.S. Department of Commerce's Economics and Statistics Administration report, STEM: Good Jobs Now and for the Future. ESA Issue Brief #03–11. July 2011.

[3] The University of Chicago Consortium of Chicago School Research (June 2012). Teaching Adolescents to Become Learners: The Role of Noncognitive Factors in Shaping School Performance. *Available at: https://ccsr.uchicago.edu/sites/default/files/publications/Noncognitive%20Report.pdf.*

[4] Walton, GM; Cohen, GL. (2011) *A Brief Social-Belonging Intervention Improves Academic and Health Outcomes of Minority Students.* Science, 331 (6023): 1447–1451. and Cohen, G.L., Garcia, J., Purdie-Vaugns, V., Apfel, N., & Brzustoski, P. (2009). *Recursive processes in self-affirmation: Intervening to close the minority achievement gap.* Science, 324, 400–403.

this notice) and for information on the other eligibility and program requirements.

The i3 program includes a statutory requirement for a private-sector match for all i3 grantees. For Development grants, an applicant must obtain matching funds or in-kind donations from the private sector equal to at least 15 percent of its grant award. Each highest-rated applicant, as identified by the Department following peer review of the applications, must submit evidence of at least 50 percent of the required private-sector match prior to the awarding of an i3 grant. An applicant must provide evidence of the remaining 50 percent of the required private-sector match no later than three months after the project start date (*i.e.,* for the FY 2015 competition, three months after January 1, 2016, or by April 1, 2016). The grant will be terminated if the grantee does not secure its private-sector match by the established deadline.

This notice also includes selection criteria for the FY 2015 Development competition that are designed to ensure that applications selected for funding have the best potential to generate substantial improvements in student achievement (and other key outcomes), and include well-articulated plans for the implementation and evaluation of the proposed projects. Applicants should review the selection criteria and submission instructions carefully to ensure their applications address this year's criteria.

An entity that submits a full application for a Development grant must include the following information in its application: An estimate of the number of students to be served by the project; evidence of the applicant's ability to implement and appropriately evaluate the proposed project; and information about its capacity (*e.g.,* management capacity, financial resources, qualified personnel) to implement the project at the proposed level of scale. We recognize that LEAs are not typically responsible for taking their processes, products, strategies, or practices to scale; however, all applicants can and should develop plans to potentially take them to scale, as well as partner with others to disseminate their effective processes, products, strategies, and practices.

The Department will screen applications that are submitted for Development grants in accordance with the requirements in this notice and determine which applications meet eligibility and other requirements. Peer reviewers will review all applications for Development grants that are submitted by the established deadline.

Applicants should note, however, that we may screen for eligibility at multiple points during the competition process, including before and after peer review; and applicants that are determined to be ineligible will not receive a grant award regardless of peer reviewer scores or comments. If we determine that a Development grant application is not supported by evidence of promise (as defined in this notice) or a strong theory (as defined in this notice), or that the applicant does not demonstrate the required prior record of improvement, or does not meet any other i3 requirement, the application will not be considered for funding.

Priorities: This competition includes five absolute priorities and one competitive preference priority. Absolute Priorities 2 and 5 and the Competitive Preference Priority are from the notice of final priorities, requirements, definitions, and selection criteria for this program, published in the **Federal Register** on March 27, 2013 (78 FR 18681) (the ''2013 i3 NFP''). Absolute Priorities 1, 3, and 4 are from the Department's notice of final supplemental priorities and definitions (Supplemental Priorities), published in the **Federal Register** on December 10, 2014 (79 FR 73425).

Absolute Priorities: For FY 2015 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, these priorities are absolute priorities. Under 34 CFR 75.105(c)(3) we consider only applications that meet one of these priorities.

Under the Development grant competition, each of the five absolute priorities constitutes its own funding category. The Secretary intends to award grants under each absolute priority for which applications of sufficient quality are submitted.

An applicant for a Development grant must choose one of the five absolute priorities to address in its pre-application, and full application, if the applicant is invited to, or chooses to, submit a full application. Both pre-applications and full applications will be peer reviewed and scored; and because scores will be rank ordered by absolute priority, it is essential that an applicant clearly identify the specific absolute priority that the proposed project addresses. It is also important to note that applicants who choose to submit an application under the absolute priority for Serving Rural Communities must identify an additional absolute priority. Regardless, the peer-reviewed scores for applications submitted under the Serving Rural Communities priority will be ranked with other applications under its priority, and not included in the ranking for the additional priority that the applicant identified. This design helps us ensure that applicants under the Serving Rural Communities priority receive an ''apples to apples'' comparison with other rural applicants.

These priorities are:

Absolute Priority 1— Improving the Effectiveness of Principals

Under this priority, we provide funding to projects that are designed to increase the number and percentage of highly effective principals by implementing practices or strategies that support districts in hiring, evaluating, supporting, and retaining effective principals.

For the purposes of this priority, principal effectiveness must be measured using a high-quality principal evaluation and support system (as defined in this notice).

Absolute Priority 2—Improving Science, Technology, Engineering, and Mathematics (STEM) Education

Under this priority, we provide funding to projects that address the following priority area:

Expanding high-quality out-of-school and extended-day activities, including extending the day, week, or year, or before- or after- school, or summer learning programs, that provide students with opportunities for deliberate practice that increase STEM learning, engagement, and expertise.

Absolute Priority 3— Leveraging Technology To Support Instructional Practice and Professional Development

Under this priority, we provide funding to projects that are designed to leverage technology through using data platforms that enable the development, visualization, and rapid analysis of data to inform and improve learning outcomes, while also protecting privacy in accordance with applicable laws.

Absolute Priority 4—Influencing the Development of Non-Cognitive Factors

Under this priority, we provide funding to projects that are designed to improve students' mastery of non-cognitive skills and behaviors (such as academic behaviors, academic mindset, perseverance, self-regulation, social and emotional skills, and approaches toward learning strategies) and enhance student motivation and engagement in learning.

Absolute Priority 5—Serving Rural Communities

Under this priority, we provide funding to projects that address one of

the absolute priorities established for the 2015 Development i3 competition and under which the majority of students to be served are enrolled in rural local educational agencies (as defined in this notice).

Competitive Preference Priority: For FY 2015 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is a competitive preference priority. Under 34 CFR 75.105(c)(2)(i) we award an additional three points to an application that meets the competitive preference priority.

The priority is:

Competitive Preference Priority—Supporting Novice i3 Applicants (Zero or 3 Points)

Eligible applicants that have never directly received a grant under this program.

Definitions

The definition for ''high-quality principal evaluation and support system'' is from the Supplemental Priorities. The definitions of ''evidence of promise,'' ''logic model,'' ''national level,'' ''quasi-experimental design study,'' ''randomized controlled trial,'' ''regional level,'' ''relevant outcome,'' ''strong theory'' and ''What Works Clearinghouse Evidence Standards'' are from 34 CFR 77.1. All other definitions are from the 2013 i3 NFP. We may apply these definitions in any year in which this program is in effect.

Consortium of schools means two or more public elementary or secondary schools acting collaboratively for the purpose of applying for and implementing an i3 grant jointly with an eligible nonprofit organization.

Evidence of promise means there is empirical evidence to support the theoretical linkage(s) between at least one critical component and at least one relevant outcome presented in the logic model for the proposed process, product, strategy, or practice. Specifically, evidence of promise means the conditions in both paragraphs (i) and (ii) of this definition are met:

(i) There is at least one study that is a—

(A) Correlational study with statistical controls for selection bias;

(B) Quasi-experimental design study that meets the What Works Clearinghouse Evidence Standards with reservations; or

(C) Randomized controlled trial that meets the What Works Clearinghouse Evidence Standards with or without reservations.

(ii) The study referenced in paragraph (i) of this definition found a statistically significant or substantively important (defined as a difference of 0.25 standard deviations or larger) favorable association between at least one critical component and one relevant outcome presented in the logic model for the proposed process, product, strategy, or practice.

High-minority school is defined by a school's LEA in a manner consistent with the corresponding State's Teacher Equity Plan, as required by section 1111(b)(8)(C) of the Elementary and Secondary Education Act of 1965, as amended (ESEA). The applicant must provide, in its i3 application, the definition(s) used.

High-need student means a student at risk of educational failure or otherwise in need of special assistance and support, such as students who are living in poverty, who attend high-minority schools (as defined in this notice), who are far below grade level, who have left school before receiving a regular high school diploma, who are at risk of not graduating with a diploma on time, who are homeless, who are in foster care, who have been incarcerated, who have disabilities, or who are English learners.

High school graduation rate means a four-year adjusted cohort graduation rate consistent with 34 CFR 200.19(b)(1) and may also include an extended-year adjusted cohort graduation rate consistent with 34 CFR 200.19(b)(1)(v) if the State in which the proposed project is implemented has been approved by the Secretary to use such a rate under Title I of the ESEA.

High-quality principal evaluation and support system means a system that provides for continuous improvement of instruction; differentiates performance using at least three performance levels; uses multiple valid measures to determine performance levels, including data on Student Growth as a significant factor and other measures of professional practice; evaluates principals on a regular basis; provides clear and timely feedback that identifies needs and guides professional development; is developed with teacher and principal involvement; and is used to inform personnel decisions.

Independent evaluation means that the evaluation is designed and carried out independent of, but in coordination with, any employees of the entities who develop a process, product, strategy, or practice and are implementing it.

Innovation means a process, product, strategy, or practice that improves (or is expected to improve) significantly upon the outcomes reached with status quo options and that can ultimately reach widespread effective usage.

Logic model (also referred to as theory of action) means a well-specified conceptual framework that identifies key components of the proposed process, product, strategy, or practice (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the relationships among the key components and outcomes, theoretically and operationally.

National level describes the level of scope or effectiveness of a process, product, strategy, or practice that is able to be effective in a wide variety of communities, including rural and urban areas, as well as with different groups (*e.g.,* economically disadvantaged, racial and ethnic groups, migrant populations, individuals with disabilities, English learners, and individuals of each gender).

Nonprofit organization means an entity that meets the definition of ''nonprofit'' under 34 CFR 77.1(c), or an institution of higher education as defined by section 101(a) of the Higher Education Act of 1965, as amended.

Quasi-experimental design study means a study using a design that attempts to approximate an experimental design by identifying a comparison group that is similar to the treatment group in important respects. These studies, depending on design and implementation, can meet What Works Clearinghouse Evidence Standards with reservations (but not What Works Clearinghouse Evidence Standards without reservations).

Randomized controlled trial means a study that employs random assignment of, for example, students, teachers, classrooms, schools, or districts to receive the intervention being evaluated (the treatment group) or not to receive the intervention (the control group). The estimated effectiveness of the intervention is the difference between the average outcomes for the treatment group and for the control group. These studies, depending on design and implementation, can meet What Works Clearinghouse Evidence Standards without reservations.

Regional level describes the level of scope or effectiveness of a process, product, strategy, or practice that is able to serve a variety of communities within a State or multiple States, including rural and urban areas, as well as with different groups (*e.g.,* economically disadvantaged, racial and ethnic groups, migrant populations, individuals with disabilities, English learners, and individuals of each gender). For an LEA-based project to be considered a

regional-level project, a process, product, strategy, or practice must serve students in more than one LEA, unless the process, product, strategy, or practice is implemented in a State in which the State educational agency is the sole educational agency for all schools.

Relevant outcome means the student outcome(s) (or the ultimate outcome if not related to students) the proposed process, product, strategy or practice is designed to improve; consistent with the specific goals of a program.

Rural local educational agency means a local educational agency (LEA) that is eligible under the Small Rural School Achievement (SRSA) program or the Rural and Low-Income School (RLIS) program authorized under Title VI, Part B of the ESEA. Eligible applicants may determine whether a particular LEA is eligible for these programs by referring to information on the Department's Web site at *www2.ed.gov/nclb/freedom/local/reap.html*.

Strong theory means a rationale for the proposed process, product, strategy, or practice that includes a logic model (as defined in this notice).

Student achievement means—

(a) For grades and subjects in which assessments are required under ESEA section 1111(b)(3): (1) A student's score on such assessments and may include (2) other measures of student learning, such as those described in paragraph (b), provided they are rigorous and comparable across schools within an LEA.

(b) For grades and subjects in which assessments are not required under ESEA section 1111(b)(3): Alternative measures of student learning and performance such as student results on pre-tests, end-of-course tests, and objective performance-based assessments; student learning objectives; student performance on English language proficiency assessments; and other measures of student achievement that are rigorous and comparable across schools within an LEA.

Student growth means the change in student achievement (as defined in this notice) for an individual student between two or more points in time. An applicant may also include other measures that are rigorous and comparable across classrooms.

What Works Clearinghouse Evidence Standards means the standards set forth in the What Works Clearinghouse Procedures and Standards Handbook (Version 3.0, March 2014), which can be found at the following link: *http://ies.ed.gov/ncee/wwc/DocumentSum.aspx?sid=19*.

Program Authority: American Recovery and Reinvestment Act of 2009, Division A, Section 14007, Pub. L. 111–5.

Applicable Regulations: (a) EDGAR in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended in 2 CFR part 3474. (d) 2013 i3 NFP (78 FR 18681). (e) The Supplemental Priorities (79 FR 73425).

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Cooperative agreements or discretionary grants.

Estimated Available Funds: $112,400,000.

These estimated available funds are the total available for all three types of grants under the i3 program (Development, Validation, and Scale-up grants). Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2016 or later years from the list of unfunded applicants from this competition.

Estimated Range of Awards

Development grants: Up to $3,000,000.
Validation grants: Up to $12,000,000.
Scale-up grants: Up to $20,000,000.

Note: The upper limit of the range of awards (*e.g.,* $3,000,000 for development grants) is referred to as the ''maximum amount of awards'' in section 5 of this notice.

Estimated Average Size of Awards

Development grants: $3,000,000.
Validation grants: $11,500,000.
Scale-up grants: $19,000,000.

Estimated Number of Awards

Development grants: 9–11 awards.
Validation grants: 2–4 awards.
Scale-up grants: 0–1 awards.

Note: The Department is not bound by any estimates in this notice.

Project Period: 36–60 months.

III. Eligibility Information

1. *Innovations that Improve Achievement for High-Need Students:* All grantees must implement practices that are designed to improve student achievement (as defined in this notice) or student growth (as defined in this notice), close achievement gaps, decrease dropout rates, increase high school graduation rates (as defined in this notice), or increase college enrollment and completion rates for high-need students (as defined in this notice).

2. *Innovations that Serve Kindergarten-through-Grade-12 (K–12) Students:* All grantees must implement practices that serve students who are in grades K–12 at some point during the funding period. To meet this requirement, projects that serve early learners (*i.e.,* infants, toddlers, or preschoolers) must provide services or supports that extend into kindergarten or later years, and projects that serve postsecondary students must provide services or supports during the secondary grades or earlier.

3. *Eligible Applicants:* Entities eligible to apply for i3 grants include either of the following:

(a) An LEA.

(b) A partnership between a nonprofit organization and—

(1) One or more LEAs; or

(2) A consortium of schools.

Statutory Eligibility Requirements: Except as specifically set forth in the *Note about Eligibility for an Eligible Applicant that Includes a Nonprofit Organization* that follows, to be eligible for an award, an eligible applicant must—

(a)(1) Have significantly closed the achievement gaps between groups of students described in section 1111(b)(2) of the ESEA (economically disadvantaged students, students from major racial and ethnic groups, students with limited English proficiency, students with disabilities); or

(2) Have demonstrated success in significantly increasing student academic achievement for all groups of students described in that section;

(b) Have made significant improvements in other areas, such as high school graduation rates (as defined in this notice) or increased recruitment and placement of high-quality teachers and principals, as demonstrated with meaningful data;

(c) Demonstrate that it has established one or more partnerships with the private sector, which may include philanthropic organizations, and that organizations in the private sector will provide matching funds in order to help bring results to scale; and

(d) In the case of an eligible applicant that includes a nonprofit organization, provide in the application the names of

the LEAs with which the nonprofit organization will partner, or the names of the schools in the consortium with which it will partner. If an eligible applicant that includes a nonprofit organization intends to partner with additional LEAs or schools that are not named in the application, it must describe in the application the demographic and other characteristics of these LEAs and schools and the process it will use to select them.

Note: An entity submitting an application should provide, in Appendix C, under ''Other Attachments Form,'' of its application, information addressing the eligibility requirements described in this section. An applicant must provide, in its application, sufficient supporting data or other information to allow the Department to determine whether the applicant has met the eligibility requirements. Note that in order to address the statutory eligibility requirement above, applicants must provide data that demonstrate a change. In other words, applicants must provide data for at least two points in time when addressing this requirement in Appendix C of their applications. If the Department determines that an applicant has provided insufficient information in its application, the applicant will not have an opportunity to provide additional information.

Note about LEA Eligibility: For purposes of this program, an LEA is an LEA located within one of the 50 States, the District of Columbia, or the Commonwealth of Puerto Rico.

Note about Eligibility for an Eligible Applicant that Includes a Nonprofit Organization: The authorizing statute specifies that an eligible applicant that includes a nonprofit organization meets the requirements in paragraphs (a) and (b) of the eligibility requirements for this program if the nonprofit organization has a record of significantly improving student achievement, attainment, or retention. For an eligible applicant that includes a nonprofit organization, the nonprofit organization must demonstrate that it has a record of significantly improving student achievement, attainment, or retention through its record of work with an LEA or schools. Therefore, an eligible applicant that includes a nonprofit organization does not necessarily need to include as a partner for its i3 grant an LEA or a consortium of schools that meets the requirements in paragraphs (a) and (b) of the eligibility requirements in this notice.

In addition, the authorizing statute specifies that an eligible applicant that includes a nonprofit organization meets the requirements of paragraph (c) of the eligibility requirements in this notice if the eligible applicant demonstrates that it will meet the requirement for private-sector matching.

4. *Cost Sharing or Matching:* To be eligible for an award, an applicant must demonstrate that one or more private-sector organizations, which may include philanthropic organizations, will provide matching funds in order to help bring project results to scale. An eligible Development applicant must obtain matching funds, or in-kind donations, equal to at least 15 percent of its Federal grant award. The highest-rated eligible applicants must submit evidence of 50 percent of the required private-sector matching funds following the peer review of applications. A Federal i3 award will not be made unless the applicant provides adequate evidence that the 50 percent of the required private-sector match has been committed or the Secretary approves the eligible applicant's request to reduce the matching-level requirement. An applicant must provide evidence of the remaining 50 percent of required private-sector match three months after the project start date.

The Secretary may consider decreasing the matching requirement on a case-by-case basis, and only in the most exceptional circumstances. An eligible applicant that anticipates being unable to meet the full amount of the private-sector matching requirement must include in its application a request that the Secretary reduce the matching-level requirement, along with a statement of the basis for the request.

Note: An applicant that does not provide a request for a reduction of the matching-level requirement in its full application may not submit that request at a later time.

5. *Other:* The Secretary establishes the following requirements for the i3 program. These requirements are from the 2013 i3 NFP. We may apply these requirements in any year in which this program is in effect.

• *Evidence Standards:* To be eligible for an award, an application for a Development grant must be supported by evidence of promise (as defined in this notice) or a strong theory (as defined in this notice). Applicants must identify in Appendix D and the Applicant Information Sheet if their evidence is supported by evidence of promise or a strong theory.

Note: In Appendix D, under the ''Other Attachments Form,'' an entity that submits a full application should provide information addressing one of the required evidence standards for Development grants. This information should include a description of the intervention(s) the applicant plans to implement and the intended student outcomes that the intervention(s) attempts to impact.

Applicants must identify in Appendix D and the Applicant Information Sheet if their evidence is supported by evidence of promise or a strong theory. An applicant submitting its Development grant application under the evidence of promise standard should identify up to two study citations to be reviewed for the purposes of meeting the i3 evidence standard requirement and include those citations in Appendix D. In addition, the applicant should specify the intervention that they plan to implement, the findings within the citations that the applicant is requesting be considered as evidence of promise, including page number(s) of specific tables if applicable. The Department will not consider a study citation that an applicant fails to clearly identify for review.

An applicant must either ensure that all evidence is available to the Department from publicly available sources and provide links or other guidance indicating where it is available; or, in the full application, include copies of evidence in Appendix D. If the Department determines that an applicant has provided insufficient information, the applicant will not have an opportunity to provide additional information at a later time.

Note: The evidence standards apply to the prior research that supports the effectiveness of the proposed project. The i3 program does not restrict the source of prior research providing evidence for the proposed project. As such, an applicant could cite prior research in Appendix D for studies that were conducted by another entity (*i.e.,* an entity that is not the applicant) so long as the prior research studies cited in the application are relevant to the effectiveness of the proposed project. If an applicant applies under the evidence of promise standard but does not meet it, their application will not be reviewed under the strong theory standard.

• *Funding Categories:* An applicant will be considered for an award only for the type of i3 grant (*i.e.,* Development, Validation, and Scale-up grants) for which it applies. An applicant may not submit an application for the same proposed project under more than one type of grant.

• *Limit on Grant Awards:* (a) No grantee may receive more than two new grant awards of any type under the i3 program in a single year; (b) in any two-year period, no grantee may receive more than one new Scale-up or Validation grant; and (c) no grantee may receive in a single year new i3 grant awards that total an amount greater than the sum of the maximum amount of funds for a Scale-up grant and the maximum amount of funds for a Development grant for that year. For example, in a year when the maximum award value for a Scale-up grant is $20 million and the maximum award value

for a Development grant is $3 million, no grantee may receive in a single year new grants totaling more than $23 million.

• *Subgrants:* In the case of an eligible applicant that is a partnership between a nonprofit organization and (1) one or more LEAs or (2) a consortium of schools, the partner serving as the applicant and, if funded, as the grantee, may make subgrants to one or more entities in the partnership.

• *Evaluation:* The grantee must conduct an independent evaluation (as defined in this notice) of its project. This evaluation must estimate the impact of the i3-supported practice (as implemented at the proposed level of scale) on a relevant outcome (as defined in this notice). The grantee must make broadly available digitally and free of charge, through formal (*e.g.,* peer-reviewed journals) or informal (*e.g.,* newsletters) mechanisms, the results of any evaluations it conducts of its funded activities.

In addition, the grantee and its independent evaluator must agree to cooperate with any technical assistance provided by the Department or its contractor and comply with the requirements of any evaluation of the program conducted by the Department. This includes providing to the Department, within 100 days of a grant award, an updated comprehensive evaluation plan in a format and using such tools as the Department may require. Grantees must update this evaluation plan at least annually to reflect any changes to the evaluation. All of these updates must be consistent with the scope and objectives of the approved application.

• *Communities of Practice:* Grantees must participate in, organize, or facilitate, as appropriate, communities of practice for the i3 program. A community of practice is a group of grantees that agrees to interact regularly to solve a persistent problem or improve practice in an area that is important to them.

• *Management Plan:* Within 100 days of a grant award, the grantee must provide an updated comprehensive management plan for the approved project in a format and using such tools as the Department may require. This management plan must include detailed information about implementation of the first year of the grant, including key milestones, staffing details, and other information that the Department may require. It must also include a complete list of performance metrics, including baseline measures and annual targets. The grantee must update this management plan at least annually to reflect implementation of subsequent years of the project.

IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application package via the Internet or from the Education Publications Center (ED Pubs). To obtain a copy via the Internet, use the following address: *www2.ed.gov/programs/innovation/index.html.* To obtain a copy from ED Pubs, write, fax, or call the following: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *www.EDPubs.gov* or at its email address: *edpubs@inet.ed.gov.*

If you request an application package from ED Pubs, be sure to identify this program or competition as follows: CFDA number 84.411P (for pre-applications) or 84.411C (for full applications).

Individuals with disabilities can obtain a copy of the application package in an accessible format (*e.g.,* Braille, large print, audiotape, or compact disc) by contacting the person or team listed under *Accessible Format* in section VIII of this notice.

2.a. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition.

Deadline for Notice of Intent to Submit Application: April 20, 2015.

We will be able to develop a more efficient process for reviewing grant applications if we know the approximate number of applicants that intend to apply for funding under this competition. Therefore, the Secretary strongly encourages each potential applicant to notify us of the applicant's intent to submit an application by completing a Web-based form. When completing this form, applicants will provide (1) the applicant organization's name and address and (2) the one absolute priority the applicant intends to address. Applicants may access this form online at *https://www.surveymonkey.com/s/9QXGZS7.* Applicants that do not complete this form may still submit a pre-application. Page Limit: For the pre-application, the project narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your pre-application. For the full application, the project narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your full applications.

Pre-Application page limit: Applicants should limit the pre-application narrative to no more than seven pages.

Full-Application page limit: Applicants submitting a full application should limit the application narrative [Part III] for a Development grant application to no more than 25 pages. Applicants are also strongly encouraged not to include lengthy appendices for the full application that contain information that they were unable to include in the narrative. Aside from the required forms, applicants should not include appendices in their pre-applications. Applicants for both pre- and full applications should use the following standards:

• A ''page'' is 8.5″ × 11″, on one side only, with 1″ margins at the top, bottom, and both sides.

• Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions.

• Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).

• Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The page limit for the full application does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support for the full application. However, the page limit does apply to all of the application narrative section [Part III] of the full application.

b. *Submission of Proprietary Information:*

Given the types of projects that may be proposed in applications for the i3 program, some applications may include business information that applicants consider proprietary. The Department's regulations define ''business information'' in 34 CFR 5.11.

Consistent with the process followed in the prior i3 competitions, we plan on posting the project narrative section of funded i3 applications on the Department's Web site so you may wish to request confidentiality of business information. Identifying proprietary information in the submitted application will help facilitate this public disclosure process.

Consistent with Executive Order 12600, please designate in your application any information that you feel is exempt from disclosure under Exemption 4 of the Freedom of Information Act. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Submission Dates and Times:*

Pre-Applications Available: April 1, 2015.

Deadline for Notice of Intent to Submit Pre-Application: April 20, 2015.

Informational Meetings: The i3 program intends to hold Webinars designed to provide technical assistance to interested applicants for all three types of grants. Detailed information regarding these meetings will be provided on the i3 Web site at *www2.ed.gov/programs/innovation/index.html.*

Deadline for Transmittal of Pre-Applications: April 29, 2015.

Deadline for Transmittal of Full Applications: The Department will announce on its Web site the deadline date for transmission of full applications for Development grants. Under the pre-application process, peer reviewers will read and score the shorter pre-application against an abbreviated set of selection criteria, and entities that submit highly rated pre-applications will be invited to submit full applications for a Development grant. Other pre-applicants may choose to submit a full application.

Pre- and full applications for Development grants under this competition must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV. 7. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review of Full Applications: 60 calendar days after the deadline date for transmittal of full applications.

4. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the System for Award Management (SAM) (formerly the Central Contractor Registry (CCR)), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet. A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data entered into the SAM database by an entity. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

Note: Once your SAM registration is active, you will need to allow 24 to 48 hours for the information to be available in Grants.gov and before you can submit an application through Grants.gov.

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at *www.SAM.gov.* To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account, we have prepared a SAM.gov Tip Sheet, which you can find at: *www2.ed.gov/fund/grant/apply/sam-faqs.html.*

In addition, if you are submitting your application via Grants.gov, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with Grants.gov as an AOR. Details on these steps are outlined at the following Grants.gov Web page: *www.grants.gov/web/grants/register.html.*

7. *Other Submission Requirements:* Applications for grants for the i3 program must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. Electronic Submission of Applications

Applications (both pre- and full applications) for Development grants under the i3 program, CFDA Number 84.411P (pre-applications) and CFDA Number 84.411C (full applications), must be submitted electronically using the Governmentwide Grants.gov Apply site at *www.Grants.gov.* Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement and submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for the i3 program at

www.Grants.gov. You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (*e.g.,* search for 84.411, not 84.411P or 84.411C).

Please note the following:

• When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.

• Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30:00 p.m., Washington, DC time, on the application deadline date.

• The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.

• You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this competition to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov under News and Events on the Department's G5 system home page at *www.G5.gov.*

• You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.

• You must submit all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.

• You must upload any narrative sections and all other attachments to your application as files in a PDF (Portable Document) read-only, non-modifiable format. Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF or submit a password-protected file, we will not review that material.

• Your electronic application must comply with any page-limit requirements described in this notice.

• After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by email. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).

• We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues With the Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1–800–518–4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

• You do not have access to the Internet; or

• You do not have the capacity to upload large documents to the Grants.gov system; *and*

• No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Kelly Terpak, U.S. Department of Education, 400 Maryland Avenue SW., Room 4C107, Washington, DC 20202–5930. FAX: (202) 205–5631.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. Submission of Paper Applications by Mail

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the

Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.411C or 84.411P), LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

Note: Entities submitting pre-applications for Development grants will use CFDA Number 84.411P, and entities submitting full applications for Development grants will use CFDA Number 84.411C.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. Submission of Paper Applications by Hand Delivery

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.411C or 84.411P), 550 12th Street SW., Room 7039, Potomac Center Plaza, Washington, DC 20202–4260.

Note: Entities submitting pre-applications for Development grants will use 84.411P, and entities submitting full applications for Development grants will use 84.411C.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* This competition has separate selection criteria for pre-applications and full applications. The selection criteria for the Development competition are from the 2013 i3 NFP and 34 CFR 75.210, and are listed below.

The points assigned to each criterion are indicated in the parentheses next to the criterion. An applicant may earn up to a total of 20 points based on the selection criteria for the pre-application. An applicant may earn up to a total of 100 points based on the selection criteria for the full application.

Note: An applicant must provide information on how its proposed project addresses the selection criteria in the project narrative section of its application. In responding to the selection criteria, applicants submitting both pre- and full applications should keep in mind that peer reviewers may consider only the information provided in the written application when scoring and commenting on the application. Therefore, applicants should draft their responses with the goal of helping peer reviewers understand the following:

- What the applicant is proposing to do, including the absolute priority under which the applicant intends the application to be reviewed;
- How the proposed project will improve upon existing processes, products, strategies, or practices for addressing similar needs;
- What the outcomes of the project will be if it is successful; and
- What procedures are in place for ensuring feedback and continuous improvement in the operation of the proposed project.

Selection Criteria for the Development Grant Pre-Application

A. Significance (Up to 10 Points)

In determining the significance of the project, the Secretary considers the extent to which the proposed project involves the development or demonstration of promising new strategies that build on, or are alternatives to, existing strategies. (34 CFR 75.210)

B. Quality of Project Design (Up to 10 Points)

In determining the quality of the proposed project design, the Secretary considers the extent to which the goals, objectives, and outcomes to be achieved by the project are clearly specified and measured. (34 CFR 75.210)

Selection Criteria for the Development Grant Full Application

A. Significance (Up to 35 Points)

In determining the significance of the project, the Secretary considers the following factors:

(1) The extent to which the proposed project involves the development or demonstration of promising new strategies that build on, or are alternatives to, existing strategies.

(2) The national significance of the proposed project.

(3) The potential replicability of the proposed project or strategies, including, as appropriate, the potential for implementation in a variety of settings. (34 CFR 75.210)

B. Quality of the Project Design and Management Plan (Up to 45 Points)

In determining the quality of the proposed project design, the Secretary considers the following factors:

(1) The extent to which the goals, objectives, and outcomes to be achieved by the project are clearly specified and measurable.

(2) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(3) The adequacy of procedures for ensuring feedback and continuous improvement in the operation of the proposed project.

(4) The mechanisms the applicant will use to broadly disseminate information on its project so as to support further development or replication. (34 CFR 75.210)

C. Quality of Project Evaluation (Up to 20 Points)

In determining the quality of the project evaluation to be conducted, the Secretary considers the following factors:

(1) The clarity and importance of the key questions to be addressed by the project evaluation, and the appropriateness of the methods for how each question will be addressed. (2013 i3 NFP)

(2) The extent to which the methods of evaluation will, if well-implemented,

produce evidence about the project's effectiveness that would meet the What Works Clearinghouse Evidence Standards with reservations. (34 CFR 75.210)

(3) The extent to which the proposed project plan includes sufficient resources to carry out the project evaluation effectively. (2013 i3 NFP)

Note: Applicants are encouraged to design an evaluation that will report findings on English Learners, students with disabilities, and other subgroups. Additionally, applicants may wish to review the following technical assistance resources on evaluation: (1) WWC Procedures and Standards Handbook: *http://ies.ed.gov/ncee/wwc/references/idocviewer/doc.aspx?docid=19&tocid=1*; and (2) IES/NCEE Technical Methods papers: *http://ies.ed.gov/ncee/tech_methods/*. In addition, we invite applicants to view an optional Webinar recording that was hosted by the Institute of Education Sciences on March 3, 2015. This Webinar discussed strategies for designing and executing well-designed quasi-experimental design studies. Applicants interested in viewing this Webinar may find more information at the following Web site: *http://ies.ed.gov/ncee/wwc/news.aspx?sid=23.*

2. *Review and Selection Process:* In order to receive an i3 Development grant, an entity must submit a pre-application. The pre-application will be reviewed and scored by peer reviewers using the two selection criteria established in this notice. We will inform the entities that submitted pre-applications of the results of the peer review process. Entities with highly rated pre-applications will be invited to submit full applications. Other pre-applicants may choose to submit a full application. Scores received on pre-applications will not carry over to the review of the full application.

As described earlier in this notice, before making awards, we will screen applications submitted in accordance with the requirements in this notice to determine which applications have met eligibility and other statutory requirements. This screening process may occur at various stages of the pre-application and full application processes; applicants that are determined ineligible will not receive a grant, regardless of peer reviewer scores or comments.

For the pre- and full application review processes, we will use independent peer reviewers with varied backgrounds and professions including pre-kindergarten-grade 12 teachers and principals, college and university educators, researchers and evaluators, social entrepreneurs, strategy consultants, grant makers and managers, and others with education expertise. All reviewers will be thoroughly screened for conflicts of interest to ensure a fair and competitive review process.

Peer reviewers will read, prepare a written evaluation, and score the assigned pre-applications and full applications, using the respective selection criteria provided in this notice. For Development grant pre-applications, peer reviewers will review and score the applications based on the two selection criteria for pre-applications listed in the *Selection Criteria for the Development Grant Pre-Application* section of this notice. For full applications submitted for Development grants, peer reviewers will review and score the applications based on the three selection criteria for full applications listed in the *Selection Criteria for the Development Grant Full Application* section of this notice. If an eligible applicant chooses to address the competitive preference priority (Supporting Novice i3 Applicants) to earn competitive preference priority points, the Department will review its list of previous i3 grantees in scoring this competitive preference priority.

We remind potential applicants that, in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Special Conditions:* Under 2 CFR 3474.10, the Secretary may impose special conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

4. *Performance Measures:* The overall purpose of the i3 program is to expand the implementation of, and investment in, innovative practices that are demonstrated to have an impact on improving student achievement or student growth for high-need students. We have established several performance measures for the i3 Development grants.

Short-term performance measures: (1) The percentage of grantees whose projects are being implemented with fidelity to the approved design; (2) the percentage of programs, practices, or strategies supported by a Development grant with ongoing evaluations that provide evidence of their promise for improving student outcomes; (3) the percentage of programs, practices, or strategies supported by a Development grant with ongoing evaluations that are

providing high-quality implementation data and performance feedback that allow for periodic assessment of progress toward achieving intended outcomes; and (4) the cost per student actually served by the grant.

Long-term performance measures: (1) The percentage of programs, practices, or strategies supported by a Development grant with a completed evaluation that provides evidence of their promise for improving student outcomes; (2) the percentage of programs, practices, or strategies supported by a Development grant with a completed evaluation that provides information about the key elements and approach of the project so as to facilitate further development, replication, or testing in other settings; and (3) the cost per student for programs, practices, or strategies that were proven promising at improving educational outcomes for students.

5. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application. In making a continuation grant, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Kelly Terpak, U.S. Department of Education, 400 Maryland Avenue SW., Room 4C107, Washington, DC 20202–5930. Telephone: (202) 453–7122. FAX: (202) 205–5631 or by email: *i3@ed.gov.*

If you use a TDD or a TTY, call the Federal Relay Service, toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* Braille, large print, audiotape, or compact disc) on request to either program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: March 25, 2015.

Nadya Chinoy Dabby,

Associate Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. 2015–07213 Filed 3–27–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Staff Attendance at South Carolina Regional Transmission Planning Meeting

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of its staff may attend the meeting of the South Carolina Regional Planning (SCRTP) Stakeholder Group, as noted below. Their attendance is part of the Commission's ongoing outreach efforts.

SCRTP March 30, 2015 (10 a.m.–1 p.m.), Old Santee Canal Park, Interpretive Center—Canal Room, 900 Stony Landing Drive, Moncks Corner, SC 29461. The facility's phone number is (843) 899–5200.

The discussions may address matters at issue in the following proceedings:

Docket No. ER13–107, *South Carolina Electric & Gas Company*

Docket No. ER13–1935, *South Carolina Electric & Gas Company*

Docket No. ER13–1928, *Duke Energy Carolinas/Carolina Power & Light*

Docket No. ER13–1930, *Louisville Gas & Electric Company/Kentucky Utilities*

Docket No. ER13–1940, *Ohio Valley Electric Corporation*

Docket No. ER13–1941, *Southern Companies*

The meeting is open to the public.

For more information, contact Mike Lee, Office of Energy Market Regulation, Federal Energy Regulatory Commission at (202) 502–8658 or *Michael.Lee@ferc.gov.*

Dated: March 19, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–07141 Filed 3–27–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Proposed Subsequent Arrangement

AGENCY: Office of Nonproliferation and Arms Control, Department of Energy.

ACTION: Proposed subsequent arrangement.

SUMMARY: This document is being issued under the authority of the Atomic Energy Act of 1954, as amended. The Department is providing notice of a proposed subsequent arrangement under the Agreement for Cooperation Concerning Civil Uses of Nuclear Energy Between the Government of the United States of America and the Government of Canada and the Agreement for Cooperation in the Peaceful Uses of Nuclear Energy Between the United States of America and the European Atomic Energy Community.

DATES: This subsequent arrangement will take effect no sooner than April 14, 2015.

FOR FURTHER INFORMATION CONTACT: Ms. Katie Strangis, Office of Nonproliferation and Arms Control, National Nuclear Security Administration, Department of Energy. Telephone: 202–586–8623 or email: *Katie.Strangis@nnsa.doe.gov.*

SUPPLEMENTARY INFORMATION: This subsequent arrangement concerns the retransfer of 221,893 kg of U.S.-origin natural uranium hexafluoride (UF6) (67.6% U), 150,000 kg of which is uranium, from Cameco Corporation (Cameco) in Saskatoon, Saskatchewan, to Urenco Ltd. (URENCO) in Almelo, The Netherlands. The material, which is currently located at Cameco in Port Hope, Ontario, will be used for toll enrichment by URENCO at its facility in Almelo, The Netherlands. The material was originally obtained by Cameco from Power Resources, Inc., Cameco Resources-Crowe Butte Operation, and White Mesa Mill pursuant to export license XSOU8798.

In accordance with section 131a. of the Atomic Energy Act of 1954, as amended, it has been determined that

this subsequent arrangement concerning the retransfer of nuclear material of United States origin will not be inimical to the common defense and security of the United States of America.

Dated: March 11, 2015.

For the Department of Energy.

Anne M. Harrington,

Deputy Administrator, Defense Nuclear Nonproliferation.

[FR Doc. 2015–07214 Filed 3–27–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Commission Staff Attendance

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of the Commission's staff may attend the following meeting related to the transmission planning activities of the Southern Company Services, Inc.

The Southeastern Regional Transmission Planning (SERTP) Process First Quarter Meeting.

March 26, 2015, 10:00 a.m.–1:00 p.m. (Central Time)

The above-referenced meeting will be via web conference.

The above-referenced meeting is open to stakeholders.

Further information may be found at: *www.southeasternrtp.com.*

The discussions at the meeting described above may address matters at issue in the following proceedings:

Docket Nos. ER13–83, ER13–1928, *Duke Energy Carolinas/Carolina Power & Light*

Docket Nos. ER13–908, ER13–1941, *Alabama Power Company et al.*

Docket Nos. ER13–913, ER13–1940, *Ohio Valley Electric Corporation*

Docket Nos. ER13–897, ER13–1930, *Louisville Gas and Electric Company and Kentucky Utilities Company*

Docket Nos. ER13–107, ER13–1935, *South Carolina Electric & Gas Company*

Docket Nos. ER13–80, ER13–1932, *Tampa Electric Company*

Docket No. ER13–86, *Florida Power Corporation*

Docket Nos. ER13–104, ER13–1929, *Florida Power & Light Company*

Docket No. ER13–1922, *Duke Energy Florida (Progress Energy Florida)*

Docket Nos. ER13–195, ER13–198, ER13–1927, ER13–1936, *PJM Interconnection, L.L.C.*

Docket No. ER13–90, *Public Service Electric and Gas Company and PJM Interconnection, L.L.C.*

For more information, contact Valerie Martin, Office of Energy Market Regulation, Federal Energy Regulatory Commission at (202) 502–6139 or *Valerie.Martin@ferc.gov.*

Dated: March 19, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–07142 Filed 3–27–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2142–038]

Brookfield White Pine Hydro, LLC; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Recreation Plan Amendment.

b. *Project No:* 2142–038.

c. *Date Filed:* March 11, 2015.

d. *Applicant:* Brookfield White Pine Hydro, LLC.

e. *Name of Project:* Indian Pond Project.

f. *Location:* The project is located on the Kennebec River in Big Squaw, Chase Stream, and Indian Stream townships, in Somerset and Piscataquis Counties, Maine. The project does not occupy any federal lands.

g. *Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Mr. Jason Seyfried, Brookfield White Pine Hydro, LLC, 26 Katherine Drive, Hallowell, Maine 04347, telephone: 207–629–1883 or email: *jason.seyfried@brookfieldrenewable.com.*

i. *FERC Contact:* Mr. Lorance Yates at 678–245–3084 or email: *lorance.yates@ferc.gov.*

j. *Deadline for filing comments and/or motions:* April 23, 2015.

All documents may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Please include the project number (P–2142–038) on any comments, motions, or recommendations filed.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Application:* Brookfield White Pine Hydro proposes revisions to its recreational facility use fees as outlined in Section 4.0 of the Indian Pond Project's approved recreation plan. This plan was approved by the Commission's, ''Order Modifying and Approving Revised Recreation Plan'' under article 405 issued on February 23, 2005 (110 FERC ¶ 62,166). The licensee proposes to ''charge a reasonable rate for use of the recreational facilities, in general accordance with the licensee's cost to operate and maintain the facilities,'' except for those recreational facilities uniquely specified in the July 25, 2001 Settlement Agreement.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling 202–502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits (P–2142) in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call 202–502–8659. A copy is also available for inspection and

reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: March 24, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–07205 Filed 3–27–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TS15–1–000]

City of Alexandria, Louisiana; Notice of Filing

Take notice that on December 31, 2014, the City of Alexandria, Louisiana filed a motion requesting full waiver of reciprocity-based Open Access Transmission Tariff (OATT), Open Access Same Time Information System (OASIS), and Standards of Conduct requirements that might otherwise apply to Alexandria under Order Nos. 888,[1] 889,[2] 890,[3] 2004,[4] and 717 [5] and part 385 of the Commission's regulations.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street N.E., 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 April 14, 2015.

Dated: March 24, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–07195 Filed 3–27–15; 8:45 am]

BILLING CODE 6717–01–P

[1] *Promoting Wholesale Competition Through Open Access Non-Discriminatory Transmission Services by Public Utilities; Recovery of Stranded Costs by Public Utilities and Transmitting Utilities,* Order No. 888, FERC Stats. & Regs. ¶ 31,036 (1996), *order on reh'g,* Order No. 888–A, FERC Stats. & Regs. ¶ 31,048, *order on reh'g,* Order No. 888–B, 81 FERC ¶ 61,248 (1997), *order on reh'g,* Order No. 888–C, 82 FERC ¶ 61,046 (1998), *aff'd in relevant part sub nom. Transmission Access Policy Study Group* v. *FERC,* 225 F.3d 667 (D.C. Cir. 2000), *aff'd sub nom. New York* v. *FERC,* 535 U.S. 1 (2002) (Order No. 888).

[2] *Open Access Same-Time Information System (formerly Real-Time Information Networks) and Standards of Conduct,* Order No. 889, FERC Stats. & Regs. ¶ 31,035 (1996), *order on reh'g,* Order No. 889–A, FERC Stats. & Regs. ¶ 31,049 (1997), *order on reh'g,* Order No. 889–B, 81 FERC ¶ 61,253 (1997).

[3] *Preventing Undue Discrimination and Preference in Transmission Service,* Order No. 890, FERC Stats. & Regs. ¶ 31,241, *order on reh'g,* Order No. 890–A, FERC Stats. & Regs. ¶ 31,261 (2007), *order on reh'g,* Order No. 890–B, 123 FERC ¶ 61,299 (2008), *order on reh'g,* Order No. 890–C, 126 FERC ¶ 61,228 (2009) *order on reh'g,* Order No. 890–D, 129 FERC ¶ 61,126 (2009) (Order No. 890).

[4] *Standards of Conduct for Transmission Providers,* Order No. 2004, FERC Stats. & Regs. ¶ 31,155 (2003), *order on reh'g,* Order No. 2004–A, FERC Stats. & Regs. ¶ 31,161, *order on reh'g,* Order No. 2004–B, FERC Stats. & Regs. ¶ 31,166, *order on reh'g,* Order No. 2004–C, FERC Stats. & Regs. ¶ 31,172 (2004), *order on reh'g,* Order No. 2004–D, 110 FERC ¶ 61,320 (2005), *vacated and remanded as it applies to natural gas pipelines sub nom. National Fuel Gas Supply Corp.* v. *FERC,* 468 F.3d 831 (D.C. Cir. 2006); *see Standards of Conduct for Transmission Providers,* Order No. 690, FERC Stats. & Regs. ¶ 31,237, *order on reh'g,* Order No. 690–A, FERC Stats. & Regs. ¶ 31,243 (2007); *see also* Order No. 717, FERC Stats. & Regs. ¶ 31,280.

[5] *Standards of Conduct for Transmission Providers,* Order No. 717, FERC Stats. & Regs. ¶ 31,280 (2008) *order on reh'g,* Order No. 717–A, FERC Stats. & Regs. ¶ 31,297 (2009) *order on reh'g,* Order No. 717–B, 129 FERC ¶ 61,123 (2009).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15–91–000]

East Tennessee Natural Gas, LLC; Notice of Intent To Prepare an Environmental Assessment for the Proposed Loudon Expansion Project and Request for Comments on Environmental Issues

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Loudon Expansion Project involving construction and operation of facilities by East Tennessee Natural Gas, LLC (East Tennessee) in Monroe and Loudon Counties, Tennessee. The Commission will use this EA in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the project. Your input will help the Commission staff determine what issues they need to evaluate in the EA. Please note that the scoping period will close on April 23, 2015.

Further details on how to submit written comments are in the Public Participation section of this notice. If you sent comments on this project to the Commission before the opening of this

docket on February 20, 2015, you will need to file those comments in Docket No. CP15–91–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the project, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

East Tennessee provided landowners with a fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. It is also available for viewing on the FERC Web site (*www.ferc.gov*).

Summary of the Proposed Project

East Tennessee would construct, own, and operate a new pipeline and related appurtenant facilities extending from its existing 12-inch-diameter Line 3200–1 pipeline in Monroe County, Tennessee to Tate & Lyle Americas Ingredients, LLC (Tate & Lyle) a manufacturer of artificial sweeteners and ethanol products in Loudon County, Tennessee. The Loudon Expansion Project would provide up to 40,000 decatherms per day of natural gas to Tate & Lyle, which is planning to convert its existing coal fired boilers to natural gas, and install a new natural gas fueled combined cycle electric power plant.

The Loudon Expansion Project would consist of the following facilities:

- About 10 miles of 12-inch-diameter pipeline (Loudon Mainline Extension) in Monroe and Loudon Counties;
- A new 12-inch mainline valve, two 12-inch tee taps and related appurtenant facilities at the interconnection of the Loudon Mainline Extension with the existing Line 3200–1 mainline in Monroe County;
- A new meter facility and related appurtenances located at the end of the Loudon Mainline Extension at the Tate & Lyle Plant in Loudon County, Tennessee;
- Above- and below-ground piping, flow measurement equipment, flow control equipment, filter/separator, pig launcher and receiver,[1] aboveground valve operators for belowground valves, blowdowns, and a condensate tank; and
- A new pressure regulator at existing meter station 59039 on East Tennessee's existing Loudon-Lenoir City Lateral Line 3218D–100, in Loudon County.

The general location of the project facilities is shown in appendix 1.[2]

Land Requirements for Construction

Construction of the proposed facilities would disturb about 88.5 acres of land. Following construction, East Tennessee would maintain about 62.3 acres for permanent operation of the project's facilities; the remaining acreage would be restored and revert to former uses. About 87 percent of the pipeline route parallels existing pipeline, utility, or road rights-of-way.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us [3] to discover and address concerns the public may have about proposals. This process is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. We will consider all filed comments during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

- Geology and soils;
- Land use;
- Water resources and fisheries, and wetlands;
- Cultural resources;
- Vegetation and wildlife, including migratory birds;
- Air quality and noise;
- Endangered and threatened species; and
- Public safety.

We will also evaluate reasonable alternatives to the project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

The EA will present our independent analysis of the issues. The EA will be available in the public record through eLibrary. Depending on the comments received during the scoping process, we may also publish and distribute the EA to the public for an allotted comment period. We will consider all comments on the EA before making our recommendations to the Commission. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section beginning on page 5.

With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate with us in the preparation of the EA.[4] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for Section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with the Tennessee State Historic Preservation Office (SHPO), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.[5] We will define the project-specific Area of Potential Effects (APE) in consultation with the SHPO as the project develops. On natural gas

[1] A ''pig'' is a tool that the pipeline company inserts into and pushes through the pipeline for cleaning the pipeline, conducting internal inspections, or other purposes.

[2] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary'' or from the Commission's Public Reference Room, 888 First Street NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to pages 6 and 7 of this notice.

[3] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

[4] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

[5] The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EA for this project will document our findings on the impacts on historic properties and summarize the status of consultations under Section 106.

Currently Identified Environmental Issues

We have already identified several issues that we think deserve attention based on a preliminary review of the proposed facilities and the environmental information provided by East Tennessee. This preliminary list of issues may be changed based on your comments and our analysis. These include impacts on:

- Waterbodies;
- Karst geology, including caves;
- Soils;
- Migratory birds;
- Vegetation;
- Candidate and listed threatened or endangered species;
- Land use;
- Air quality and noise;
- Safety; and
- Alternative routes.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please send your comments so that the Commission receives them in Washington, DC on or before April 23, 2015.

For your convenience, there are three methods which you can use to submit your comments to the Commission. In all instances please reference the project docket number (CP15–91–000) with your submission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov.*

(1) You can file your comments electronically using the *eComment* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* This is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You can file your comments electronically using the *eFiling* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''*eRegister.''* You must select the type of filing you are making. If you are filing a comment on a particular project, please select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

If we publish and distribute the EA, copies will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the attached Information Request (appendix 2).

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an ''intervenor'' which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are in the User's Guide under the ''e-filing'' link on the Commission's Web site.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site at *www.ferc.gov* using the ''eLibrary'' link. Click on the eLibrary link, click on ''General Search'' and enter the docket number, excluding the last three digits in the Docket Number field (*i.e.,* CP15–91). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission now offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Finally, public meetings or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: March 24, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–07202 Filed 3–27–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15–87–000]

Columbia Gas Transmission, LLC; Notice of Intent To Prepare an Environmental Assessment for the Proposed UTICA Access Project and Request for Comments on Environmental Issues

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Utica Access Project involving construction and operation of facilities by Columbia Gas Transmission, LLC. (Columbia) in Clay and Kanawha Counties, West Virginia. The Commission will use this EA in its decision-making process to determine

whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the project. Your input will help the Commission staff determine what issues they need to evaluate in the EA. Please note that the scoping period will close on April 20, 2015.

You may submit comments in written form. Further details on how to submit written comments are in the Public Participation section of this notice. If you sent comments on this project to the Commission before the opening of this docket on February 12, 2015, you will need to file those comments in Docket No. CP15–87–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the project, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

Columbia provided landowners with a fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. It is also available for viewing on the FERC Web site (*www.ferc.gov*).

Summary of the Proposed Project

According to Columbia, the Utica Access Project would result in a capacity of 205,000 dekatherms per day of firm transportation service of stranded Utica natural gas into Columbia's system and regional market.

Specifically, the Utica Access Project would consist of the installation of approximately 4.8 miles of new 24-inch-diameter pipeline and the following appurtenant facilities in Clay and Kanawha Counties, West Virginia:

- Four new bi-directional pig launcher and receiver systems at the following locations: one each at MP 0.0 and MP 4.8 of the new 24-inch-diameter pipeline, and one each at the existing Coco and Cobb Compressor Stations (which are on Columbia's existing Line X52–M1);
- a new mainline valve setting on Line X52–M1 at a proposed new tap at MP 0.0;
- two new 10-inch pressure regulating valves and modifications within the existing Coco Compressor Station;
- one new remote terminal unit building at MP 4.8;
- twenty-one existing and two partially new access roads; and
- three temporary contractor yards.

The general location of the project facilities is shown in appendix 1. [1]

Land Requirements for Construction

The total land requirement to construct the project is approximately 118.9 acres, of which 36.6 acres would be permanently altered and converted to pipeline right-of-way, access road, or commercial/industrial land use. Upland forest would make up approximately 27.2 acres of the 36.6 acres of permanent impacts. Upon completion of the project, the remaining land used for temporary workspace would be re-graded, stabilized and re-vegetated, and allowed to revert to pre-construction conditions.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us [2] to discover and address concerns the public may have about proposals. This process is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. We will consider all filed comments during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

- Land use;
- geology and soils;
- water resources, fisheries, and wetlands;
- cultural resources;
- vegetation and wildlife;
- air quality and noise;
- endangered and threatened species;
- public safety; and
- cumulative impacts.

We will also evaluate reasonable alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

The EA will present our independent analysis of the issues. The EA will be available in the public record through eLibrary. Depending on the comments received during the scoping process, we may also publish and distribute the EA to the public for an allotted comment period. We will consider all comments on the EA before making our recommendations to the Commission. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section below.

With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate with us in the preparation of the EA.[3] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for Section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with the West Virginia State Historic Preservation Office (SHPO), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's

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[2] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

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potential effects on historic properties.[4] We will define the project-specific Area of Potential Effects (APE) in consultation with the SHPO as the project develops. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EA for this project will document our findings on the impacts on historic properties and summarize the status of consultations under Section 106.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please send your comments so that the Commission receives them in Washington, DC on or before April 20, 2015.

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Finally, public meetings or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: March 20, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–07143 Filed 3–27–15; 8:45 am]

BILLING CODE 6717–01–P

[4] The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

DEPARTMENT OF ENERGY

Bonneville Power Administration

Hooper Springs Transmission Project

AGENCY: Bonneville Power Administration (BPA), Department of Energy (DOE).

ACTION: Notice of availability of Record of Decision (ROD).

SUMMARY: This notice announces the availability of the ROD to implement the Hooper Springs Transmission Project in Caribou County, Idaho. BPA has decided to implement the South Alternative's Option 3A (Option 3A) identified in the Hooper Springs Transmission Project Final Environmental Impact Statement (DOE/EIS–0451, January 2015). Option 3A consists of: (1) A new 138/115-kilovolt (kV) Hooper Springs Substation located near the city of Soda Springs, Idaho; (2) a new, approximately 24-mile-long, double-circuit 115-kV transmission line extending generally north then east from the Hooper Springs Substation to a new BPA connection facility that will connect the new line to Lower Valley Energy's (LVE) existing transmission system in northeastern Caribou County; (3) a new, approximately 0.2-mile-long, single-circuit 138-kV transmission line extending generally south from the Hooper Springs Substation to

PacifiCorp's existing Threemile Knoll Substation to connect the new line to the regional transmission grid; and (4) required ancillary facilities such as access roads.

The new Hooper Springs Substation will be constructed as a 138/115-kV substation, meaning that it will include a transformer capable of converting 138-kV electricity to 115-kV electricity. BPA will acquire 100-foot-wide right-of-way for the length of the 115-kV line. Approximately 174 new double-circuit 115-kV steel structures, ranging in height from 55 to 120 feet with an average span length between structures of 730 feet, will be installed in this new right-of-way. The BPA connection facility will be located about two miles southeast of the intersection of Blackfoot River Road and Diamond Creek Road and will consist of overhead line disconnect switches to connect the new 115-kV line to the existing LVE line. For the single-circuit 138-kV transmission line, two wood, H-frame structures approximately 80 to 85 feet tall will be installed within a new 125-foot-wide right-of-way. A fiber optic cable also will be installed along the 138-kV transmission line. About 14 miles of new access roads will be constructed and about 2.4 miles of existing access roads will be improved or reconstructed. All mitigation measures identified in the EIS are adopted.

ADDRESSES: Copies of the ROD and EIS may be obtained by calling BPA's toll-free document request line, 1–800–622–4520. The ROD and EIS are also available on our Web site, *http://efw.bpa.gov/environmental_services/Document_Library/HooperSprings/.*

FOR FURTHER INFORMATION CONTACT: Tish Eaton, Bonneville Power Administration—KEC–4, P.O. Box 3621, Portland, Oregon 97208–3621; toll-free telephone number 1–800–622–4519; fax number 503–230–5699; or email *tkeaton@bpa.gov.*

Issued in Portland, Oregon on March 16, 2015.

Elliot E. Mainzer,

Administrator and Chief Executive Officer.

[FR Doc. 2015–07199 Filed 3–27–15; 8:45 am]

BILLING CODE 6450–01–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: RP15–656–000.
Applicants: Transcontinental Gas Pipe Line Company.
Description: Section 4(d) rate filing per 154.403: LSS and SS–2 Fuel Tracker Filing 2015 to be effective 4/1/2015.
Filed Date: 3/18/15.
Accession Number: 20150318–5147.
Comments Due: 5 p.m. ET 3/30/15.

Docket Numbers: RP15–657–000.
Applicants: Equitrans, L.P.
Description: Section 4(d) rate filing per 154.204: Negotiated Capacity Release Agreement—3/19/2015 to be effective 3/19/2015.
Filed Date: 3/19/15.
Accession Number: 20150319–5025.
Comments Due: 5 p.m. ET 3/31/15.

Docket Numbers: RP15–658–000.
Applicants: Enable Gas Transmission, LLC.
Description: Section 4(d) rate filing per 154.204: Negotiated Rate Filing—SND Non-Conforming 0414 (RS FT) to be effective 2/1/2015.
Filed Date: 3/19/15.
Accession Number: 20150319–5132.
Comments Due: 5 p.m. ET 3/31/15.

Docket Numbers: RP15–659–000.
Applicants: Portland Natural Gas Transmission System.
Description: Compliance filing per 154.203: Compliance to Order 801—Docket No. RM14–21–000 to be effective 6/1/2015.
Filed Date: 3/20/15.
Accession Number: 20150320–5022.
Comments Due: 5 p.m. ET 4/1/15.

Docket Numbers: RP15–660–000.
Applicants: Gulf South Pipeline Company, LP.
Description: Section 4(d) rate filing per 154.204: Amendments to Neg Rate Agmts (QEP 37657–137, 36601–40) to be effective 3/20/2015.
Filed Date: 3/20/15.
Accession Number: 20150320–5023.
Comments Due: 5 p.m. ET 4/1/15.

Docket Numbers: RP15–661–000.
Applicants: Natural Gas Pipeline Company of America.
Description: Section 4(d) rate filing per 154.204: Negotiated Rate—Occidental Energy to be effective 4/1/2015.
Filed Date: 3/20/15.
Accession Number: 20150320–5117.
Comments Due: 5 p.m. ET 4/1/15.

Docket Numbers: RP15–662–000.
Applicants: Leaf River Energy Center LLC.
Description: Compliance filing per 154.203: Leaf River Energy Center LLC—Order No. 801 Compliance Filing to be effective 4/1/2015.
Filed Date: 3/20/15.
Accession Number: 20150320–5154.
Comments Due: 5 p.m. ET 4/1/15.

Docket Numbers: RP15–663–000.
Applicants: ANR Storage Company.
Description: Compliance filing per 154.203: Compliance to Order 801—Docket No. RM14–21–000 to be effective 6/1/2015.
Filed Date: 3/23/15.
Accession Number: 20150323–5052.
Comments Due: 5 p.m. ET 4/6/15.

Docket Numbers: RP15–664–000.
Applicants: Blue Lake Gas Storage Company.
Description: Compliance filing per 154.203: Compliance to Order 801—Docket No. RM14–21–000 to be effective 6/1/2015.
Filed Date: 3/23/15.
Accession Number: 20150323–5053.
Comments Due: 5 p.m. ET 4/6/15.

Docket Numbers: RP15–665–000.
Applicants: Bison Pipeline LLC.
Description: Compliance filing per 154.203: Compliance to Order 801—Docket No. RM14–21–000 to be effective 6/1/2015.
Filed Date: 3/23/15.
Accession Number: 20150323–5054.
Comments Due: 5 p.m. ET 4/6/15.

Docket Numbers: RP15–666–000.
Applicants: Horizon Pipeline Company, L.L.C.
Description: Penalty Revenue Crediting Report of Horizon Pipeline Company, L.L.C.
Filed Date: 3/20/15.
Accession Number: 20150320–5266.
Comments Due: 5 p.m. ET 4/1/15.

Docket Numbers: RP15–667–000.
Applicants: Midcontinent Express Pipeline LLC.
Description: Penalty Revenue Crediting Report of Midcontinent Express Pipeline LLC.
Filed Date: 3/20/15.
Accession Number: 20150320–5267.
Comments Due: 5 p.m. ET 4/1/15.

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: RP13–1371–002.
Applicants: Eastern Shore Natural Gas Company.
Description: Compliance filing per 154.203: Compliance with Order No. 801 to be effective 4/1/2015.
Filed Date: 3/19/15.
Accession Number: 20150319–5042.
Comments Due: 5 p.m. ET 3/31/15.

Docket Numbers: RP15–584–001.
Applicants: Rockies Express Pipeline LLC.
Description: Tariff Amendment per 154.205(b): Errata to RP15–584 to be effective 4/1/2015.
Filed Date: 3/23/15.
Accession Number: 20150323–5000.
Comments Due: 5 p.m. ET 4/6/15.

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: March 23, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–07164 Filed 3–27–15; 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: EC15–102–000.
Applicants: Florida Power & Light Company.
Description: Application of Florida Power & Light Company for Authorization Under Section 203 of the Federal Power Act and Request for Expedited Action.
Filed Date: 3/23/15.
Accession Number: 20150323–5346.
Comments Due: 5 p.m. ET 4/13/15.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG15–70–000.
Applicants: CPV Biomass Holdings, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of CPV Biomass Holdings, LLC.
Filed Date: 3/24/15.
Accession Number: 20150324–5086.
Comments Due: 5 p.m. ET 4/14/15.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–3184–004; *ER10–2805–004; ER10–2600–005; ER10–2564–005; ER10–2289–005; EL15–42–000.*
Applicants: FortisUS Energy Corporation, Central Hudson Gas & Electric Corp., Tucson Electric Power Company, UNS Electric, Inc., UniSource Energy Development Company.
Description: Response to Order to Show Cause of the Fortis MBR Sellers.
Filed Date: 3/23/15.
Accession Number: 20150323–5342.
Comments Due: 5 p.m. ET 4/13/15.

Docket Numbers: ER11–4315–005; *ER10–3110–004; ER10–3144–005.*
Applicants: Gila River Power LLC, Union Power Partners, L.P., Entegra Power Services LLC.
Description: Notice of Non-Material Change in Status of the Entegra Public Utilities.
Filed Date: 3/24/15.
Accession Number: 20150324–5159.
Comments Due: 5 p.m. ET 4/14/15.

Docket Numbers: ER13–1922–001.
Applicants: Duke Energy Florida, Inc., Duke Energy Carolinas, LLC.
Description: Compliance filing per 35: Order No. 1000 Interregional FRCC & SERTP to be effective 1/1/2015.
Filed Date: 3/24/15.
Accession Number: 20150324–5070.
Comments Due: 5 p.m. ET 4/14/15.

Docket Numbers: ER13–1928–002.
Applicants: Duke Energy Progress, Inc., Duke Energy Carolinas, LLC.
Description: Compliance filing per 35: Order No. 1000 Interregional—SERTP & SCRTP & FRCC to be effective 1/1/2015.
Filed Date: 3/24/15.
Accession Number: 20150324–5069.
Comments Due: 5 p.m. ET 4/14/15.

Docket Numbers: ER13–1930–002.
Applicants: Louisville Gas and Electric Company.
Description: Compliance filing per 35: Order 1000 Interregional FRCC and SCRTP to be effective 1/1/2015.
Filed Date: 3/24/15.
Accession Number: 20150324–5092.
Comments Due: 5 p.m. ET 4/14/15.

Docket Numbers: ER13–1932–001.
Applicants: Tampa Electric Company.
Description: Compliance filing per 35: OATT Order No. 1000 Interregional Compliance Filing 2015 to be effective 1/1/2015.
Filed Date: 3/24/15.
Accession Number: 20150324–5034.
Comments Due: 5 p.m. ET 4/14/15.

Docket Numbers: ER13–1935–001.
Applicants: South Carolina Electric & Gas Company.
Description: Compliance filing per 35: Order 1000 Interregional Compliance filing 3–24–15 to be effective 1/1/2015.
Filed Date: 3/24/15.
Accession Number: 20150324–5057.
Comments Due: 5 p.m. ET 4/14/15.

Docket Numbers: ER13–1941–002.
Applicants: Alabama Power Company.
Description: Compliance filing per 35: Order No. 1000 Second Interregional Compliance Filing—FRCC & SCRPT Seams to be effective 1/1/2015.
Filed Date: 3/24/15.
Accession Number: 20150324–5074.
Comments Due: 5 p.m. ET 4/14/15.

Docket Numbers: ER13–2255–001.
Applicants: Mansfield Power and Gas, LLC.
Description: Notice of Non-Material Change in Status of Mansfield Power and Gas, LLC.
Filed Date: 3/18/15.
Accession Number: 20150318–5204.
Comments Due: 5 p.m. ET 4/8/15.

Docket Numbers: ER13–2318–005; *ER13–2317–005; ER13–2319–005.*
Applicants: All Dams Generation, LLC, Lake Lynn Generation, LLC, PE Hydro Generation, LLC.
Description: Notification of Change in Status of the Cube Hydro MBR Sellers.
Filed Date: 3/23/15.
Accession Number: 20150323–5343.
Comments Due: 5 p.m. ET 4/13/15.

Docket Numbers: ER14–2864–003.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Amendment per 35.17(b): Compliance Filing per 2/20/15 Order in Docket No. ER14–2864 to be effective 11/12/2015.
Filed Date: 3/23/15.
Accession Number: 20150323–5321.
Comments Due: 5 p.m. ET 4/13/15.

Docket Numbers: ER15–551–000.
Applicants: Southwest Power Pool, Inc.
Description: eTariff filing per 35.19a(b): 2390R2 Westar Energy, Inc. Refund Report to be effective N/A.
Filed Date: 3/24/15.
Accession Number: 20150324–5077.
Comments Due: 5 p.m. ET 4/14/15.

Docket Numbers: ER15–571–000.
Applicants: Southwest Power Pool, Inc.

Description: eTariff filing per 35.19a(b): 2066R3 Westar Energy, Inc. Refund Report to be effective N/A.
Filed Date: 3/24/15.
Accession Number: 20150324–5067.
Comments Due: 5 p.m. ET 4/14/15.

Docket Numbers: ER15–599–000.
Applicants: Southwest Power Pool, Inc.
Description: eTariff filing per 35.19a(b): 2562R2 Kansas Municipal Energy Authority Refund Report to be effective N/A.
Filed Date: 3/24/15.
Accession Number: 20150324–5071.
Comments Due: 5 p.m. ET 4/14/15.

Docket Numbers: ER15–1045–000.
Applicants: Pilot Hill Wind, LLC.
Description: Supplement to February 13, 2015 Pilot Hill Wind, LLC tariff filing.
Filed Date: 3/23/15.
Accession Number: 20150323–5268.
Comments Due: 5 p.m. ET 4/6/15.

Docket Numbers: ER15–1196–001.
Applicants: Nevada Power Company.
Description: Tariff Amendment per 35.17(b): OATT Energy Imbalance Market Revision (C & P) to be effective 5/15/2015.
Filed Date: 3/24/15.
Accession Number: 20150324–5130.
Comments Due: 5 p.m. ET 4/6/15.

Docket Numbers: ER15–1359–000.
Applicants: Public Service Company of Colorado.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2015–3–23_TSGT–TSA–377–0.0.0—Filing to be effective 10/1/2014.
Filed Date: 3/23/15.
Accession Number: 20150323–5291.
Comments Due: 5 p.m. ET 4/13/15.

Docket Numbers: ER15–1360–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): Original Service Agreement No. 4109; Queue No. Z1–073 to be effective 2/19/2015.
Filed Date: 3/23/15.
Accession Number: 20150323–5305.
Comments Due: 5 p.m. ET 4/13/15.

Docket Numbers: ER15–1361–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): First Revised Service Agreement No. 3831; Queue No. Z1–072 to be effective 2/19/2015.
Filed Date: 3/23/15.
Accession Number: 20150323–5320.
Comments Due: 5 p.m. ET 4/13/15.

Docket Numbers: ER15–1362–000.
Applicants: Galt Power, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): MBR Tariff Update to be effective 3/1/2015.
Filed Date: 3/24/15.
Accession Number: 20150324–5045.
Comments Due: 5 p.m. ET 4/14/15.

Docket Numbers: ER15–1363–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2015–03–24_SA 2698 Termination of OTP-Courtenay Wind Farm GIA (J262/J263) to be effective 5/24/2015.
Filed Date: 3/24/15.
Accession Number: 20150324–5046.
Comments Due: 5 p.m. ET 4/14/15.

Docket Numbers: ER15–1364–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2015–03–24_SA 768. Bill of Sale for ATC–UPPCo Agreement to be effective 5/24/2015.
Filed Date: 3/24/15.
Accession Number: 20150324–5079.
Comments Due: 5 p.m. ET 4/14/15.

Docket Numbers: ER15–1365–000.
Applicants: Morris Cogeneration, LLC.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): Reactive Power Rate Schedule to be effective 5/1/2015.
Filed Date: 3/24/15.
Accession Number: 20150324–5124.
Comments Due: 5 p.m. ET 4/14/15.

Docket Numbers: ER15–1366–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2015–03–24_SA 2761. ATC–UPPCo Common Facilities Agreement to be effective 5/24/2015.
Filed Date: 3/24/15.
Accession Number: 20150324–5133.
Comments Due: 5 p.m. ET 4/14/15.

Docket Numbers: ER15–1367–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2015–03–24_SA 768. Notice of Termination of Bill of Sale (ATC–UPPCo) to be effective 5/24/2015.
Filed Date: 3/24/15.
Accession Number: 20150324–5137.
Comments Due: 5 p.m. ET 4/14/15.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF15–549–000.
Applicants: Clark University.
Description: Form 556 of Clark University under QF15–549.
Filed Date: 3/12/15.
Accession Number: 20150312–5166.
Comments Due: None Applicable.

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: March 24, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–07194 Filed 3–27–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC15–101–000.
Applicants: American Transmission Company LLC.
Description: Application for Authority to Acquire Transmission Facilities Under Section 203 of the FPA of American Transmission Company LLC.
Filed Date: 3/23/15.
Accession Number: 20150323–5267.
Comments Due: 5 p.m. ET 4/13/15.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER15–741–001.
Applicants: PacifiCorp.
Description: Tariff Amendment per 35.17(b): PacifiCorp Energy Network Operating Agreement—Deficiency Filing to be effective 2/22/2015.
Filed Date: 3/23/15.
Accession Number: 20150323–5186.
Comments Due: 5 p.m. ET 4/13/15.

Docket Numbers: ER15–1353–000.
Applicants: PacifiCorp.
Description: Section 205(d) rate filing per 35.13(a)(2)(iii): Idaho Power Migration Agreement—LaGrande/Pocatello to be effective 3/24/2015.
Filed Date: 3/23/15.
Accession Number: 20150323–5187.
Comments Due: 5 p.m. ET 4/13/15.

Docket Numbers: ER15–1354–000.

Applicants: Lake Lynn Generation, LLC.

Description: Compliance filing per 35: Change in Status and Amended MBR Tariff to be effective 5/19/2015.

Filed Date: 3/23/15.

Accession Number: 20150323–5221.

Comments Due: 5 p.m. ET 4/13/15.

Docket Numbers: ER15–1355–000.

Applicants: All Dams Generation, LLC.

Description: Compliance filing per 35: Change in Status and Amended MBR Tariff to be effective 5/19/2015.

Filed Date: 3/23/15.

Accession Number: 20150323–5228.

Comments Due: 5 p.m. ET 4/13/15.

Docket Numbers: ER15–1356–000.

Applicants: PE Hydro Generation, LLC.

Description: Compliance filing per 35: Change in Status and Amended MBR Tariff to be effective 5/19/2015.

Filed Date: 3/23/15.

Accession Number: 20150323–5234.

Comments Due: 5 p.m. ET 4/13/15.

Docket Numbers: ER15–1357–000.

Applicants: Golden Spread Electric Cooperative, Inc.

Description: Section 205(d) rate filing per 35.13(a)(2)(iii): Amedment Filing to be effective 1/1/2015.

Filed Date: 3/23/15.

Accession Number: 20150323–5285.

Comments Due: 5 p.m. ET 4/13/15.

Docket Numbers: ER15–1358–000.

Applicants: Rochester Gas and Electric Corporation.

Description: Baseline eTariff Filing per 35.1: Certificate of Concurrence in Amended and Restated SGIA with NYISO to be effective 3/23/2015.

Filed Date: 3/23/15.

Accession Number: 20150323–5289.

Comments Due: 5 p.m. ET 4/13/15.

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: March 23, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–07153 Filed 3–27–15; 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: PR15–30–000.

Applicants: Enbridge Pipelines (Oklahoma Trasmission) L.L.C.

Description: Submits tariff filing per 284.123(b)(2) + (g): Revised SOC—No Rate Change to be effective 3/18/2015; Filing Type: 1310.

Filed Date: 3/17/15.

Accession Number: 20150317–5054.

Comments Due: 5 p.m. ET 4/7/15. 284.123(g) Protests Due: 5 p.m. ET 5/18/15.

Docket Numbers: RP15–654–000.

Applicants: Northwest Pipeline LLC.

Description: Compliance filing per 154.203: RM14–21—Map Compliance Filing to be effective 4/17/2015.

Filed Date: 3/17/15.

Accession Number: 20150317–5203.

Comments Due: 5 p.m. ET 3/30/15.

Docket Numbers: RP15–655–000.

Applicants: Union Power Partners, L.P.

Description: Joint Petition for Limited Waiver of Union Power Partners, L.P., Entergy Arkansas, Inc., Entergy Gulf States Louisiana, L.L.C., and Entergy Texas, Inc.

Filed Date: 3/17/15.

Accession Number: 20150317–5225.

Comments Due: 5 p.m. ET 3/30/15.

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 date(s). 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: March 18, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–07163 Filed 3–27–15; 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: EC15–100–000.

Applicants: Wabash Valley Power Association, Inc., Duke Energy Indiana, Inc.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of Wabash Valley Power Association, Inc., and Duke Energy Indiana, Inc.

Filed Date: 3/20/15.

Accession Number: 20150320–5272.

Comments Due: 5 p.m. ET 4/10/15.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1777–007; *ER10–2983–006; ER10–2980–006; ER15–718–002.*

Applicants: Sundevil Power Holdings, LLC, Castleton Energy Services, LLC, Castleton Power, LLC, West Valley Power, LLC.

Description: Notification of Change in Status of the Wayzata Entities.

Filed Date: 3/20/15.

Accession Number: 20150320–5278.

Comments Due: 5 p.m. ET 4/10/15.

Docket Numbers: ER10–1800–007.

Applicants: Indianapolis Power & Light Company.

Description: Notice of Non-Material Change in Status of Indianapolis Power & Light Company.

Filed Date: 3/20/15.

Accession Number: 20150320–5279.

Comments Due: 5 p.m. ET 4/10/15.

Docket Numbers: ER10–1819–009; *ER10–1820–011; ER10–1818–008; ER10–1817–009.*

Applicants: Northern States Power Company, a Minnesota corporation, Northern States Power Company, a Wisconsin corporation, Public Service Company of Colorado, Southwestern Public Service Company.

Description: Notice of Change in Status of Northern States Power Company, a Minnesota corporation, et al.

Filed Date: 3/20/15.
Accession Number: 20150320–5277.
Comments Due: 5 p.m. ET 4/10/15.

Docket Numbers: ER10–2881–019; *ER10–2882–019; ER10–2883–019; ER10–2884–019; ER10–2885–019; ER10–2641–019; ER10–2663–019; ER10–2886–019; ER13–1101–014; ER13–1541–013; ER14–787–007; ER14–661–006.*
Applicants: Alabama Power Company, Southern Power Company, Mississippi Power Company, Georgia Power Company, Gulf Power Company, Oleander Power Project, Limited Partnership, Southern Company—Florida LLC, Southern Turner Cimarron I, LLC, Spectrum Nevada Solar, LLC, Campo Verde Solar, LLC, Macho Springs Solar, LLC, SG2 Imperial Valley LLC.
Description: Notification of Non-Material of Change in Status of Alabama Power Company, et. al.
Filed Date: 3/20/15.
Accession Number: 20150320–5276.
Comments Due: 5 p.m. ET 4/10/15.

Docket Numbers: ER12–959–000.
Applicants: Southwest Power Pool, Inc.
Description: eTariff filing per 35.19a(b): Tri-County Electric Cooperative Formula Rate Refund Report in ER12–959–000 to be effective N/A.
Filed Date: 3/23/15.
Accession Number: 20150323–5142.
Comments Due: 5 p.m. ET 4/13/15.

Docket Numbers: ER13–823–003*; ER15–1348–001; ER12–1561–002.*
Applicants: Castleton Commodities Merchant Trading L, Roseton Generating LLC, CCI Rensselaer LLC.
Description: Triennial Market Power Analysis Update of Castleton Commodities Merchant Trading L.P. for the Northeast Region.
Filed Date: 3/20/15.
Accession Number: 20150320–5283.
Comments Due: 5 p.m. ET 5/19/15.

Docket Numbers: ER15–1029–001.
Applicants: Chubu TT Energy Management Inc.
Description: Tariff Amendment per 35.17(b): Chubu TT MBRA App Supplement to be effective 4/15/2015.
Filed Date: 3/20/15.
Accession Number: 20150320–5230.
Comments Due: 5 p.m. ET 4/10/15.

Docket Numbers: ER15–1351–000.
Applicants: PJM Interconnection, L.L.C.
Description: Section 205(d) rate filing per 35.13(a)(2)(iii): Service Agreement No. 3770; Queue No. X1–037 to be effective 2/19/2015 under ER15–1351 Filing Type: 10.
Filed Date: 3/23/15.
Accession Number: 20150323–5138.
Comments Due: 5 p.m. ET 4/13/15.

Docket Numbers: ER15–1352–000.
Applicants: Portsmouth Genco, LLC.
Description: Petition for Limited Waiver of Tariff Deadlines and Request for Expedited Action of Portsmouth Genco, LLC.
Filed Date: 3/23/15.
Accession Number: 20150323–5164.
Comments Due: 5 p.m. ET 4/13/15.

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: March 23, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–07152 Filed 3–27–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL15–55–000]

Modesto Irrigation District Turlock Irrigation District v. Pacific Gas and Electric Company; Notice of Complaint

Take notice that on March 18, 2015, pursuant to section 202, 206, 306 and 309 of the Federal Power Act, 16 U.S.C. 824(a), 825(e), 825(e), 825(h) and rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206 Modesto Irrigation District (Mid) and the Turlock Irrigation District (TID) (collectively, Complainants) filed a formal complaint against the Pacific Gas and Electric Company (PG&E or Respondent), alleging that PG&E has breached and anticipatorily breached each Complainants' respective Interconnection Agreements on file with the Commission, in violation of the Federal Power Act, by: (1) Failing to fully and properly notify the Complainants of modifications to Respondent's Remedial Action Scheme (RAS); (2) refusing and failing to study the potential Adverse Impacts arising from these RAS modifications; and (3) repudiating Respondent's obligation to mitigate or compensate for adverse impacts arising from such RAS modifications.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 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 electronic 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 April 7, 2015.

Dated: March 19, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–07144 Filed 3–27–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER15–402–001; Docket No. ER15–817–000; Docket No. ER15–861–000; Docket No. EL15–53–000;]

California Independent System Operator Corporation; Notice of FERC Staff Attendance

The Federal Energy Regulatory Commission (Commission) hereby gives notice that on March 26, 2015 members of its staff will attend the California Independent System Operator Corporation's (CAISO) Board of Governors meeting. The agenda and other documents for the meeting are available on CAISO's Web site, *www.caiso.com.*

Sponsored by CAISO, the meeting is open to all market participants and staff's attendance is part of the Commission's ongoing outreach efforts. The meeting may discuss matters at issue in the above captioned dockets.

For further information, contact Saeed Farrokhpay at *saeed.farrokhpay@ferc.gov* (916) 294–0322.

Dated: March 24, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–07203 Filed 3–27–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER15–861–000; EL15–53–000]

California Independent System Operator Corporation; Notice of Technical Conference

By order issued in this proceeding on March 16, 2015,[1] the Federal Energy Regulatory Commission (Commission) directed its staff to convene a technical conference to develop a record regarding issues related to imbalance energy price spikes experienced in PacifiCorp's balancing authority areas (BAAs) subsequent to PacifiCorp's full activation in the California Independent System Operator Corporation's (CAISO) Energy Imbalance Market (EIM), and to facilitate the development of a long-term solution. Consistent with the attached agenda, the technical conference will explore the circumstances identified in reports filed by CAISO and its Department of Market Monitoring (DMM) in Docket No. ER15–402–000 regarding the imbalance energy price spikes in PacifiCorp's BAAs and the status of CAISO and PacifiCorp efforts to improve the transitional issues identified in those reports. CAISO should come prepared to answer the questions laid out in the attached agenda. We invite DMM and PacifiCorp to also be prepared to answer questions.

The technical conference will be held on Thursday, April 9, 2015, from 10:00 a.m. to 5:00 p.m. (EST), at the offices of the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Attached to this notice is an agenda for the technical conference.

The technical conference will be open for the public to attend, and those interested in attending are encouraged to register by close of business, April 1, 2015. You may register at the following Web page: *https://www.ferc.gov/whats-new/registration/04-09-15-form.asp.*

An audio listen-only line will be provided. If you need a listen-only line, please email Sarah McKinley (*Sarah.McKinley@ferc.gov*) by 5:00 p.m. (EST) on Friday, April 3, with your name, email, and phone number, in order to receive the call-in information the day before the conference. Please use the following text for the subject line, ''ER15–861 listen-only line registration.''

This conference will also be transcribed. Transcripts of the technical conference will be available for a fee from Ace-Federal Reporters, Inc. (202) 347–3700.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to *accessibility@ferc.gov* or call toll free 1 (866) 208–3372 (voice) or (202) 208–1659 (TTY), or send a FAX to (202) 208–2106 with the required accommodations.

FOR FURTHER INFORMATION PLEASE CONTACT: Sarah McKinley, Office of External Affairs, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–8368, *sarah.mckinley@ferc.gov*; Jennifer B. Shipley, Office of Energy Market Regulation, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–6822, *jennifer.shipley@ferc.gov*.

Dated: March 24, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–07204 Filed 3–27–15; 8:45 am]

BILLING CODE 6717–01–P

[1] *Cal. Indep. Sys. Operator Corp.*, 150 FERC ¶ 61,191 (2015).

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2014–0734; FRL–9924–51]

Agency Information Collection Activities; Proposed Renewal and Comment Request; Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces that EPA is planning to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). The ICR, entitled: ''Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies'' and identified by EPA ICR No. 0575.15 and OMB Control No. 2070–0004, represents the renewal of an existing ICR that is scheduled to expire on November 30, 2015. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before May 29, 2015.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2014–0734, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

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

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Mike Mattheisen, Chemical Control

Division (7405–M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–3077; email address: *mattheisen.mike@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. What information is EPA particularly interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

3. Enhance the quality, utility, and clarity of the information to be collected.

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What information collection activity or ICR does this action apply to?

Title: Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies.

ICR number: EPA ICR No. 0575.15.

OMB control number: OMB Control No. 2070–0004.

ICR status: This ICR is currently scheduled to expire on November 30, 2015. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: Section 8(d) of the Toxic Substances Control Act (TSCA) and 40 CFR part 716 require manufacturers and processors of chemicals to submit lists and copies of health and safety studies relating to the health and/or environmental effects of certain chemical substances and mixtures. In order to comply with the reporting requirements of TSCA section 8(d), respondents must search their records to identify any health and safety studies in their possession, copy and process relevant studies, list studies that are currently in progress, and submit this information to EPA.

EPA uses this information to construct a complete picture of the known effects of the chemicals in question, leading to determinations by EPA of whether additional testing of the chemicals is required. The information enables EPA to base its testing decisions on the most complete information available and to avoid demands for testing that may be duplicative. EPA will use information obtained via this collection to support its investigation of the risks posed by chemicals and, in particular, to support its decisions on whether to require industry to test chemicals under section 4 of TSCA. This information collection request addresses the reporting requirements found in TSCA section 8(d).

Responses to the collection of information are mandatory (see 40 CFR part 716). Respondents may claim all or part of a response confidential. EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in TSCA section 14 and 40 CFR part 2.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 10.0 hours per response. Burden is defined in 5 CFR 1320.3(b).

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Respondents/Affected Entities: Entities potentially affected by this ICR are persons who manufacture, process, or distribute in commerce chemical substances or mixtures, or who propose to do so.

Estimated total number of potential respondents: 119.

Frequency of response: On occasion.

Estimated total average number of responses for each respondent: 1.3.

Estimated total annual burden hours: 1,605 hours.

Estimated total annual costs: $116,551. This includes an estimated burden cost of $116,551 and an estimated cost of $0 for capital investment or maintenance and operational costs.

III. Are there changes in the estimates from the last approval?

There is an increase of 242 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This increase reflects additional burden resulting from the one-time requirement for respondents to register with EPA's CDX reporting system and to establish electronic signature agreements, plus correcting the estimated number of robust summaries submitted each year. The ICR supporting statement provides a detailed analysis of the change in burden estimate. This change is an adjustment.

IV. What is the next step in the process for this ICR?

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 pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: March 20, 2015.

James Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2015–07208 Filed 3–27–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2015–0022; FRL–9924–21]

Pesticide Product Registration; Receipt of Applications for New Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before April 29, 2015.

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the File Symbol of interest as shown in the body of this document, by one of the following methods:

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

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

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (RD) (7505P), main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.* The mailing address for the contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code. The division to contact is listed at the end of each application summary.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. Registration Applications

EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications.

1. *EPA Registration Number:* 100–1254. *Docket ID number:* EPA–HQ–OPP–2015 0031. *Applicant:* Syngenta Crop Protection, 410 Swing Road, P.O. Box 18300, Greensboro, NC 27419. *Active ingredient:* Mandipropamid. *Product type:* Fungicide. *Proposed Use:* Potato seeds. *Contact:* RD.

2. *EPA Registration Number:* 100–1254. *Docket ID number:* EPA–HQ–OPP–2015–0096. *Applicant:* Syngenta Crop Protection, 410 Swing Road, P.O. Box 18300, Greensboro, NC 27419. *Active ingredient:* Mandipropamid. *Product type:* Fungicide. *Proposed Use:* Non-bearing citrus. *Contact:* RD.

3. *EPA File Symbol:* 100–RUTI. *Docket ID number:* EPA–HQ–OPP–2013–0141. *Applicant:* Syngenta Crop Protection LLC., P.O. Box 18300, Greensboro, NC 27419–8300. *Active ingredient:* Benzovindiflupyr. *Product type:* Fungicide. *Proposed uses:* Cereals; blueberries (non-bearing); corn; cotton; vegetables, cucurbits (crop group 9); fruiting vegetables (crop group 8–10); small fruit climbing subgroup 13–07F (except fuzzy kiwifruit); legume vegetables subgroup 6C; peanuts; pome fruit (crop group 11–10); rapeseed subgroup 20A; vegetables, tuberous and corm subgroup 1C; turf and ornamentals. *Contact:* RD.

4. *EPA Registration Number or File Symbol:* 8033–RGR. *Docket ID number:* EPA–HQ–OPP–2015–0124. *Applicant:* Nisso America, Inc., Nippon Soda Co., LTD., 88 Pine Street, Fourteenth Floor, New York, NY 10005. *Active ingredients:* Etofenprox, Acetamiprid, Piperonyl Butoxide, S-Methoprene. *Product type:* Spot on for dogs. *Proposed Use:* Insecticide. *Contact:* RD.

Authority: 7 U.S.C. 136 *et seq.*

Dated: March 20, 2015.

Daniel J. Rosenblatt,

Acting, Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2015–07209 Filed 3–27–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9925–26–OW]

Notice of a Public Meeting: The National Drinking Water Advisory Council (NDWAC) Lead and Copper Rule Working Group Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of a public meeting.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing a public meeting of the National Drinking Water Advisory Council (NDWAC) Lead and Copper Rule Working Group (LCRWG). The meeting is scheduled for April 23 and 24, 2015, in Arlington, VA. During this meeting, the LCRWG and EPA will focus

discussions on revising the second draft of the working group's recommendations to the NDWAC on potential changes to the Lead and Copper Rule.

DATES: The meeting on April 23, 2015, will be held from 9:00 a.m. to 5:00 p.m., eastern time, and on April 24, 2015, from 9:00 a.m. to 3:00 p.m., eastern time.

ADDRESSES: The meeting will be held at the Cadmus Group Inc., 1555 Wilson Blvd., Suite 300, Arlington, VA, and will be open to the public. All attendees must sign in with the security desk and show photo identification to enter the building.

FOR FURTHER INFORMATION CONTACT: For more information about this meeting or to request written materials contact Lameka Smith, Standards and Risk Management Division, Office of Ground Water and Drinking Water, EPA; by phone at (202) 564–1629 or by email at *LCRWorkingGroup@epa.gov.* For additional information about the Lead and Copper Rule, please visit: *http://water.epa.gov/lawsregs/rulesregs/sdwa/lcr/index.cfm.*

SUPPLEMENTARY INFORMATION:

Details about Participating in the Meeting: Members of the public who would like to register for this meeting should contact Lameka Smith by April 22, 2015, by email at *LCRWorkingGroup@epa.gov* or by phone at 202–564–1629. The LCRWG will allocate 15 minutes for the public's input at the meeting on April 23rd and 15 minutes on April 24th. Each oral statement will be limited to five minutes at the meeting. It is preferred that only one person present a statement on behalf of a group or organization. To ensure adequate time for public involvement, individuals or organizations interested in presenting an oral statement should notify Lameka Smith no later than April 21, 2015. Any person who wishes to file a written statement can do so before or after the LCRWG meeting. Written statements intended for the meeting must be received by April 20, 2015, to be distributed to all members of the working group before the meeting. Any statements received on or after the date specified will become part of the permanent file for the meeting and will be forwarded to the LCRWG members for their information.

Special Accommodations: For information on access or to request special accommodations for individuals with disabilities please contact Lameka Smith at (202) 564–1629 or by email at *LCRWorkingGroup@epa.gov* at least 10 days prior to the meeting to give the EPA as much time as possible to process your request.

Dated: March 19, 2015.

Peter Grevatt,

Director, Office of Ground Water and Drinking Water.

[FR Doc. 2015–07112 Filed 3–27–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2015–0057; FRL–9922–79]

Registration Review; Pesticide Dockets Opened for Review and Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: With this document, EPA is opening the public comment period for several registration reviews. Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. Registration review dockets contain information that will assist the public in understanding the types of information and issues that the Agency may consider during the course of registration reviews. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment. This document also announces the Agency's intent to close the registration review case for tebufenpyrad, imazamethabenz, and 2-((hydroxymethyl)-amino)ethanol (also known as HMAE). These pesticides do not currently have any actively registered pesticide products and, therefore, the Agency is closing the registration review cases for tebufenpyrad, imazamethabenz, and HMAE.

For phenmedipham, EPA is seeking comment on the preliminary work plan, the ecological problem formulation, and the human health draft risk assessment.

DATES: Comments must be received on or before May 29, 2015.

ADDRESSES: Submit your comments identified by the docket identification (ID) number for the specific pesticide of interest provided in the table in Unit III.A., by one of the following methods:

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

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

FOR FURTHER INFORMATION CONTACT:

For pesticide specific information, contact: The Chemical Review Manager for the pesticide of interest identified in the table in Unit III.A.

For general information contact: Richard Dumas, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8015; fax number: (703) 308–8005; email address: *dumas.richard@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farmworker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a

copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. Authority

EPA is initiating its reviews of the pesticides identified in this document pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136a(g)) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

III. Registration Reviews

A. What action is the Agency taking?

As directed by FIFRA section 3(g), EPA is reviewing the pesticide registrations identified in the table in this unit to assure that they continue to satisfy the FIFRA standard for registration—that is, they can still be used without unreasonable adverse effects on human health or the environment. A pesticide's registration review begins when the Agency establishes a docket for the pesticide's registration review case and opens the docket for public review and comment. At present, EPA is opening registration review dockets for the cases identified in the following table.

TABLE 1—REGISTRATION REVIEW DOCKETS OPENING

Registration review case name and No.	Pesticide docket ID No.	Chemical review manager, telephone number, email address
Bioban P-1487 (Case 3028)	EPA–HQ–OPP–2014–0802	SanYvette Williams, 703–305–7702, *williams.sanyvette@epa.gov*.
Bis(bromoacetoxy)-2-butene (BBAB) (Case 3030).	EPA–HQ–OPP–2014–0799	Tina Pham, 703–308–0125, *pham.thao@epa.gov*.
Carboxin and Oxycarboxin (Case 0012)	EPA–HQ–OPP–2015–0144	Dana L. Friedman, 703–347–8827, *friedman.dana@epa.gov*.
Copper HDO (Case 5106)	EPA–HQ–OPP–2014–0800	Donna Kamarei, 703–347–0443, *kamarei.donna@epa.gov*.
Chondrostereum Purpureum (Case 6091)	EPA–HQ–OPP–2015–0051	Kathleen Martin, 703–308–2857, *kathleen.martin@epa.gov*.
Creosote (Case 0139)	EPA–HQ–OPP–2014–0823	Sandra O'Neill, 703–347–0141, *oneill.sandra@epa.gov*.
Cyazofamid (Case 7656)	EPA–HQ–OPP–2015–0128	Jose Gayoso, 703–347–8652, *gayoso.jose@epa.gov*.
Famoxadone (Case 7038)	EPA–HQ–OPP–2015–0094	Christina Scheltema, 703–308–2201, *scheltema.christina@epa.gov*.
Lufenuron (Case 7627)	EPA–HQ–OPP–2015–0098	Bonnie Adler, 703–308–8523, *adler.bonnie@epa.gov*.
Myclobutanil (Case 7006)	EPA–HQ–OPP–2015–0053	Benjamin Askin, 703–347–0503, *askin.benjamin@epa.gov*.
Novaluron (Case 7615)	EPA–HQ–OPP–2015–0171	Margaret Hathaway, 703–305–5076, *hathaway.margaret@epa.gov*.
Phenmedipham (Case 0277)	EPA–HQ–OPP–2014–0546	Miguel Zavala, 703–347–0504, *zavala.miguel@epa.gov*.
Sethoxydim (Case 2600)	EPA–HQ–OPP–2015–0088	James Parker, 703–306–0469, *parker.james@epa.gov*.
Spirodiclofen (Case 7443)	EPA–HQ–OPP–2014–0262	Julia Stokes, 703–347–8966, *stokes.julia@epa.gov*.
Spiromesifen (Case 7442)	EPA–HQ–OPP–2014–0263	Julia Stokes, 703–347–8966, *stokes.julia@epa.gov*.

For phenmedipham (Case 0277) EPA is seeking comment on the preliminary Work Plan, the ecological problem formulation, and the human health draft risk. For Forchlorfenuron (Case 7057), EPA is seeking comment on the Combined Work Plan, Summary Document, and Proposed Interim Registration Review Decision, which includes the human health and ecological risk assessments. The Agency also is announcing the intent to close the registration review cases for tebufenpyrad, imazamethabenz, and 2-(hydroxymethyl)- amino)ethanol also known as HMAE. These pesticides do not currently have any actively registered pesticide products and, therefore, the Agency is closing the registration review cases for tebufenpyrad, imazamethabenz, and HMAE. The tebufenpyrad registration review case is being closed because the last products were canceled in the **Federal Register** notice dated September 24, 2014 (79 FR 57087) (FRL–9916–69). The ''Notice of Registration Review Case Closure'' for tebufenpyrad is available in docket EPA–HQ–OPP–2014–0218 at *http://www.regulations.gov.* For phenmedipham (Case 0277), EPA is seeking comment on the preliminary work plan, the ecological problem formulation, and the human health draft risk assessment. The imazamethabenz registration review case is being closed because the last products were canceled in the **Federal Register**. The ''Notice of Registration Review Case Closure'' for imazamethabenz is available in docket EPA–HQ–OPP–2014–0394 at *http://www.regulations.gov.*

B. Docket Content

1. *Review dockets.* The registration review dockets contain information that the Agency may consider in the course of the registration review. The Agency may include information from its files including, but not limited to, the following information:

- An overview of the registration review case status.
- A list of current product registrations and registrants.
- **Federal Register** notices regarding any pending registration actions.

- **Federal Register** notices regarding current or pending tolerances.
- Risk assessments.
- Bibliographies concerning current registrations.
- Summaries of incident data.
- Any other pertinent data or information.

Each docket contains a document summarizing what the Agency currently knows about the pesticide case and a preliminary work plan for anticipated data and assessment needs. Additional documents provide more detailed information. During this public comment period, the Agency is asking that interested persons identify any additional information they believe the Agency should consider during the registration reviews of these pesticides. The Agency identifies in each docket the areas where public comment is specifically requested, though comment in any area is welcome.

2. *Other related information.* More information on these cases, including the active ingredients for each case, may be located in the registration review schedule on the Agency's Web site at *http://www2.epa.gov/pesticide-reevaluation.* Information on the Agency's registration review program and its implementing regulation may be seen at *http://www2.epa.gov/pesticide-reevaluation/registration-review-schedules.*

3. *Information submission requirements.* Anyone may submit data or information in response to this document. To be considered during a pesticide's registration review, the submitted data or information must meet the following requirements:

- To ensure that EPA will consider data or information submitted, interested persons must submit the data or information during the comment period. The Agency may, at its discretion, consider data or information submitted at a later date.
- The data or information submitted must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audiographic or videographic record. Written material may be submitted in paper or electronic form.
- Submitters must clearly identify the source of any submitted data or information.
- Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

As provided in 40 CFR 155.58, the registration review docket for each pesticide case will remain publicly accessible through the duration of the registration review process; that is, until all actions required in the final decision on the registration review case have been completed.

Authority: 7 U.S.C. 136 *et seq.*

Dated: March 18, 2015.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2015–07200 Filed 3–27–15; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[3060–0207]

Information Collection Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before April 29, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Submit your PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202–395–5167 or via Internet at *Nicholas_A._Fraser@omb.eop.gov* and to Benish Shah, Federal Communications Commission, via the Internet at *Benish.Shah@fcc.gov.* To submit your PRA comments by email send them to: *PRA@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Benish Shah, Office of Managing Director, (202) 418–7866.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0207.

Title: Part 11—Emergency Alert System (EAS).

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Businesses or other for-profit; not-for-profit institutions; and state, local or tribal governments.

Number of Respondents and Responses: 3,569,028 respondents; 3,569,028 responses.

Estimated Time per Response: .0229776 hours.

Frequency of Response: On occasion reporting requirement and recordkeeping requirement.

Obligation to Respond: Voluntary response for business or other for-profit and not-for-respondents. Mandatory response for state, local or tribal governments. Statutory authority for this information collection is contained in 47 U.S.C. sections 154(i) and 606 of the Communications Act of 1934, as amended.

Total Annual Burden: 82,008 hours.

Total Annual Cost: N/A.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: There is no need for confidentiality.

Needs and Uses: The Commission seeking an extension of this information collection in order to obtain the full three year approval from OMB. There are no changes in any of the reporting and/or recordkeeping requirements. There is no change to the Commission's previous burden estimated.

The Commission established a voluntary electronic method of complying with the reporting that EAS participants must complete as part of the national EAS test. This electronic

submission system will impose a lesser burden on EAS test participants because they can input electronically (via a Web-based interface) the same information into a confidential database that the Commission would use to monitor and assess the test. Test participants would submit the identifying data prior to the test date. On the day of the test, EAS participants would be able to input immediate test results. They would input the remaining data called for by our reporting rules within the 45-day period. Structuring an electronic reporting system in this fashion will allow the participants to populate the database with known information prior to the test, and thus be able to provide the Commission with actual test data, both close to real-time and within a reasonable period in a minimally burdensome fashion.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of the Managing Director.

[FR Doc. 2015–07189 Filed 3–27–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0531]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before May 29, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0531.

Title: Sections 101.1011, 101.1325(b), 101.1327(a), 101.527, 101.529 and 101.103, Substantial Service Showing for Local Multipoint Distribution Service (LMDS), 24 GHz and Multiple Address System (MAS).

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities and State, local or Tribal government.

Number of Respondents: 585 respondents; 585 responses.

Estimated Time per Response: 2–20 hours.

Frequency of Response: On occasion and once every 10 years reporting requirements, and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. Sections 4(i), 303(c), 303(f), 303(g), 303(r), and 309(j) of the Communications Act of 1934, as amended.

Total Annual Burden: 1,824 hours.

Total Annual Cost: $315,150.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this information collection. Respondents may request materials or information submitted to the Commission be withheld from public inspection under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: The Commission is submitting this information collection to the Office of Management and Budget (OMB) as an extension to obtain the full three-year clearance from them. There are no changes to the reporting and third party requirements imposed on Local Multipoint Distribution Service (LMDS) respondents pursuant to 47 CFR 101.103, 101.1011 and similar reporting requirements imposed on Multiple Address System (MAS) Economic Area (EA) licensees pursuant to 47 CFR 101.1325(b), 101.1327(a), and 24 GHz licensees pursuant to 47 CFR 101.527, 101.529. This information is used by the Commission staff to satisfy requirements for licensees to demonstrate substantial service at the time of license renewal. Without this information, the Commission would not be able to carry out its statutory responsibilities. The third party disclosure coordination requirements are necessary to ensure that licensees do not cause interference to each other.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of the Managing Director.

[FR Doc. 2015–07190 Filed 3–27–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[3060–0400]

Information Collection Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of

information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before April 29, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via email *Nicholas_A._Fraser@omb.eop.gov;* and to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.* Include in the comments the OMB control number as shown in the ''Supplementary Information'' section below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Nicole Ongele at (202) 418–2991.

To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page <*http://www.reginfo.gov/public/do/PRAMain*>, (2) look for the section of the Web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0400.

Title: Part 61, Tariff Review Plan (TRP).

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 2,840 respondents; 8,554 responses.

Estimated Time per Response: 0.5 hours to 53 hours.

Frequency of Response: On occasion, annual, biennial, and one time reporting requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. Sections 201, 202, 203, and 251(b)(5) of the Communications Act of 1934, as amended.

Total Annual Burden: 121,656 hours.

Total Annual Cost: No cost.

Privacy Impact Assessment: No impact.

Nature and Extent of Confidentiality: Respondents are not being asked to submit confidential information to the Commission. If the Commission requests respondents to submit information which respondents believe are confidential, respondents may request confidential treatment of such information under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: On November 18, 2011, the Commission released the USF/ICC Transformation Order, FCC 11–61 and the Second Order on Reconsideration, FCC 12–47, released on April 25, 2012, required incumbent and competitive local exchange carriers to submit supporting documentation as part of their Tariff Review Plans (TRPs).

Certain local exchange carriers are required to submit a biennial or annual TRP in partial fulfillment of cost support material required by 47 CFR part 61. Sections 201, 202, and 203 of the Communications Act of 1934, as amended, require common carriers to establish joint and reasonable charges, practices, and regulations for their interstate telecommunications services provided. For services that are still covered under Section 203, tariff schedules containing charges, rates, rules, and regulations must be filed with the Commission. If the FCC takes no action within the notice period, then the filing becomes effective. The Commission is granted broad authority to require the submission of data showing the value of property used to provide the services, some of which are automatically required by its rules and some of which can be required through individual requests. All filings that become effective are considered legal but only those filed pursuant to Section 204(a)(3) of the Act are deemed lawful.

For services that are detariffed, no tariffs are filed at the FCC and determination of reasonableness and any unreasonable discrimination is generally addressed through the complaint process. Incumbent local exchange carriers (ILECs) can make a voluntary filing at any time, but are required to update rates annually or biennially. *See* 47 CFR 69.3.

Among other reforms, the Commission developed the TRP to minimize reporting burdens on reporting ILECs. TRPs set forth the summary material ILECs file to support revisions to the rates in their interstate access service tariffs. For those services still requiring cost support, TRPs assist the Commission in determining whether ILEC access charges are just and reasonable as required under the Communications Act of 1934, as amended.

The Commission also minimized reporting burdens by developing incentive-based regulation (price caps), which simplifies the process of determining the reasonableness of rates and rate structures for ILECs subject to price caps. Supporting material requirements for price cap ILECs having 50,000 or fewer access lines do not have to file any supporting material unless requested to do so. Price cap carriers can elect to be subject to Title I versus Title II of the Act for certain forms of internet access in order to offer their internet service on a detariffed basis pursuant to private contracts. Rate-of-return ILECs can choose to charge from tariffed to detariffed for the same internet services, but are subject to Title II regulation. Through forbearance, the Commission has allowed those LECs whose petition has been granted to choose mandatory detariffing of certain broadband and packet services.

Federal Communications Commission.

Sheryl D. Todd,

Deputy Secretary, Office of the Secretary, Office of the Managing Director.

[FR Doc. 2015–07187 Filed 3–27–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[3060–1147]

Information Collection Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other

Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before April 29, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Submit your PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202–395–5167 or via Internet at *Nicholas_A._Fraser@omb.eop.gov* and to Benish Shah, Federal Communications Commission, via the Internet at *Benish.Shah@fcc.gov*. To submit your PRA comments by email send them to: *PRA@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: Benish Shah, Office of Managing Director, (202) 418–7866.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–1147.

Title: Wireless E911 Location Accuracy Requirements.

Form Nos.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit and state, local or tribal government.

Number of Respondents: 4,294 Respondents; 4,510 Responses.

Estimated Time per Response: 1 hour to 8 hours.

Frequency of Response: On occasion reporting requirement and third party disclosure requirement.

Obligation to Respond: Mandatory. Statutory authority for this collection is contained in 47 U.S.C. Sections 151, 154, and 332 of the Communications Act of 1934, as amended.

Total Annual Burden: 31,668 hours.

Total Annual Cost: N/A.

Privacy Impact Assessment: Not applicable.

Nature and Extent of Confidentiality: No confidentiality is required for this collection.

Needs and Uses: The Commission is seeking Office of Management and Budget (OMB) approval for an extension of this information collection (no change in the reporting requirement).

The Commission has adjusted its previous burden estimates. The total annual burden has been reduced by 21,484 hours since 2012 because of fewer respondents and responses.

The Commission's *Third Report and Order* in PS Docket No. 07–114 adopted a rule, providing that new CMRS network providers, meeting the definition of covered CMRS providers in Section 20.18 and deploying new stand-alone networks subsequent to the effective date of the *Third Report and Order* that are not an expansion or upgrade of an existing CMRS network, must meet from the start the handset-based location accuracy standard in delivering emergency calls for Enhanced 911 service. The adopted rule requires that the new stand-alone CMRS providers in delivering emergency calls for Enhanced 911 service, must satisfy the handset-based location accuracy standard at either a county-based or Public Safety Answering Point (PSAP)-based geographic level. Additionally, in accordance with the pre-existing requirements for CMRS providers using handset-based location technologies, new stand-alone CMRS providers are permitted to exclude up to 15 percent of the counties or PSAP areas they serve due to heavy forestation that limits handset-based technology accuracy in those counties or areas but are required to file a an initial list of the specific counties or portions of counties where they are utilizing their respective exclusions.

A. *Updated Exclusion Reports.* Under the this information collection, and pursuant to current rule section 20.18(h), new stand- alone CMRS providers and existing CMRS providers that have filed initial exclusion reports are required to file reports informing the Commission of any changes to their exclusion lists within thirty days of discovering such changes. The permitted exclusions properly but narrowly account for the known technical limitations of either the handset-based or network-based location accuracy technologies chosen by a CMRS provider, while ensuring that the public safety community and the public at large are sufficiently informed of these limitations.

B. *Confidence and Uncertainty Data.* Under the this information collection, and pursuant to current rule section 20.18(h), all CMRS providers and other entities responsible other responsible for transporting confidence and uncertainty data between the wireless carriers and PSAPs, including LECs, CLECs, owners of E911 networks, and emergency service providers (collectively, System Service Providers (SSPs)) must continue to provide confidence and uncertainty data of wireless 911 calls to Public Safety Answering Points (PSAP) on a per call basis upon a PSAP's request. New stand-alone wireless carriers also incur this obligation. The transport of the confidence and uncertainty data is needed to ensure the delivery of accurate location information with E911 service.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of the Managing Director.

[FR Doc. 2015–07188 Filed 3–27–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Collection Renewal; Comment Request (3064–0124)

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the renewal of an existing information collection, as required by the Paperwork Reduction Act of 1995. Currently, the FDIC is soliciting comment on renewal of the information collection described below.

DATES: Comments must be submitted on or before April 29, 2015.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *http://www.FDIC.gov/regulations/laws/federal/*.

• *Email: comments@fdic.gov.* Include the name of the collection in the subject line of the message.

• *Mail:* Gary A. Kuiper, Counsel, (202.898.3877), or John Popeo, Counsel, (202.898.6923), MB–3007, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.

• *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7 a.m. and 5 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Gary A. Kuiper or John Popeo, at the FDIC address above.

SUPPLEMENTARY INFORMATION:

Proposal To Renew the Following Currently-Approved Collection of Information

1. *Title:* Notification of Changes of Insured Status.

OMB Number: 3064–0124.

Affected Public: Insured depository institutions.

Estimated Number of Respondents: 285 (certifications) and 6 (depositor notices).

Estimated Time per Response: 15 minutes (certifications); 1 hour (depositor notices).

Frequency of Response: On occasion.

Total estimated annual burden: 77.25 hours.

General Description of Collection: The collection involves the certification that insured depository institutions provide the FDIC when they completely assume deposit liabilities from another insured depository institution, and a notification that insured depository institutions provide to the FDIC when they seek to voluntarily terminate their insured status.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, this 24th day of March 2015.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2015–07096 Filed 3–27–15; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Collection Renewal; Comment Request (3064–0163)

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the renewal of an existing information collection, as required by the Paperwork Reduction Act of 1995. Currently, the FDIC is soliciting comment on renewal of the information collection described below.

DATES: Comments must be submitted on or before April 29, 2015.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

• *http://www.FDIC.gov/regulations/laws/federal/.*

• *Email: comments@fdic.gov.* Include the name of the collection in the subject line of the message.

• *Mail:* Gary A. Kuiper, Counsel, (202.898.3877), MB–3074 or John Popeo, Counsel, (202.898.6923), MB–3007, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.

• *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7 a.m. and 5 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Gary A. Kuiper or John Popeo, at the FDIC address above.

SUPPLEMENTARY INFORMATION:

Proposal To Renew the Following Currently-Approved Collection of Information

1. *Title:* Qualified Financial Contracts.

OMB Number: 3064–0163.

Affected Public: Insured depository institutions.

Estimated Number of Respondents: 190 (recordkeeping/reporting); 20 (application).

Estimated Time per Response: 64 hours (24 hours, reporting); 40 hours (recordkeeping); 30 minutes (application).

Frequency of Response: On occasion.

Estimated Total Annual Burden: 12,160 hours (recordkeeping/reporting); 10 hours (application).

Total Annual Burden: 12,170 hours.

General Description of Collection: This collection consists of reporting and recordkeeping requirements for qualified financial contracts (QFCs) held by insured depository institutions in troubled condition.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, this 24th day of March 2015.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2015–07101 Filed 3–27–15; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*)

(BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 24, 2015.

A. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *WCM-Parkway, Ltd., WCM Holdings, Inc., and Veritex Holdings, Inc.,* all in Dallas, Texas; to merge with IBT Bancorp, and thereby indirectly acquire Independent Bank of Texas, both in Irving, Texas.

Board of Governors of the Federal Reserve System, March 25, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2015–07160 Filed 3–27–15; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage *de novo,* or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 4, 2015.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *First Business Financial Services, Inc.,* Madison, Wisconsin; to engage *de novo* in certain community development activities by making a qualifying community welfare investment in a fund of funds, pursuant to section 225.28(b)(12)(i).

Board of Governors of the Federal Reserve System, March 25, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2015–07158 Filed 3–27–15; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage *de novo,* or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 4, 2015.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *First Business Financial Services, Inc.,* Madison, Wisconsin; to engage *de novo* in certain community development activities by making a qualifying community welfare investment in a fund of funds, pursuant to section 225.28(b)(12)(i).

Board of Governors of the Federal Reserve System, March 25, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2015–07170 Filed 3–27–15; 8:45 am]

BILLING CODE 6210–01–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 April 14, 2015.

A. Federal Reserve Bank of San Francisco (Gerald C. Tsai, Director, Applications and Enforcement) 101 Market Street, San Francisco, California 94105–1579:

1. *Territorial Savings Bank Employee Stock Ownership Trust and Trustees David Murakami and Richard Murakami,* all of Honolulu, Hawaii; to acquire additional voting shares of Territorial Bancorp, Inc., and thereby indirectly acquire additional voting shares of Territorial Savings Bank, both in Honolulu, Hawaii.

Board of Governors of the Federal Reserve System, March 25, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2015–07159 Filed 3–27–15; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Form CB–496: Title IV–E Programs Quarterly Financial Report.

OMB No.: 0970–0205.

Description: This is a financial report submitted following the end of each fiscal quarter by each State or Tribe with an approved title IV–E plan administering any of three title IV–E entitlement grant programs—Foster Care, Adoption Assistance or Guardianship Assistance.

The purpose of this form is to enable each State or Tribe to meet its statutory and regulatory requirement to report program expenditures made in the preceding fiscal quarter and to estimate program expenditures to be made in the upcoming fiscal quarter. This form also allows States and Tribes to report the actual and estimated average monthly number of children assisted in each of the three IV–E entitlement grant programs in the preceding and upcoming fiscal quarters, respectively.

The Administration for Children and Families provides Federal funding at the rate of 50 percent for nearly all allowable and legitimate administrative costs of these programs and at other funding rates for other specific categories of costs as detailed in Federal statute and regulations.

The information collected in this report is used by this agency to calculate quarterly Federal grant awards and to enable oversight of the financial management of the programs.

With this request, we are soliciting public comments on revising the form to incorporate changes to title IV–E programs made in accordance with the September 2014 enactment of Public Law 113–183, the ''Preventing Sex Trafficking and Strengthening Families Act.'' This includes the new requirement at section 473(a)(8)(B) of the Social Security Act to report annually on the methodology used to calculate adoption savings due to the application of differing title IV–E eligibility criteria for children designated as an ''applicable child'' under section 473(e) along with an accounting of the amount of and the expenditure of any such savings.

Respondents: States (including Puerto Rico and the District of Columbia) and Tribes * with approved title IV–E plans. (* An estimated 15 Tribes have or will have approved title IV–E plans within the next 3-year period.)

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Form CB–496: Title IV–E Programs Quarterly Financial Report	67	4	21	5,628

Estimated Total Annual Burden Hours: 5,628.

In compliance with the requirements of section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–07168 Filed 3–27–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Advisory Committee on Interdisciplinary, Community-Based Linkages; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL)

Dates and Times:

April 22, 2015 (08:30 a.m.–5:00 p.m. EST)

April 23, 2015 (08:30 a.m.–3:00 p.m. EST)

Place: Webinar and Conference Call Format

Status: The meeting will be open to the public.

Purpose: The ACICBL provides advice and recommendations to the Secretary of the Department of Health and Human Services (Secretary) concerning policy, program development, and other matters of significance related to interdisciplinary, community-based training grant programs authorized under sections 750–759, title VII, part D of the Public Health Service Act, as amended by the Affordable Care Act. The following sections are included under this part: 751—Area Health Education Centers; 752—Continuing Education Support for Health Professionals Serving in Underserved Communities; 753—Geriatrics Workforce Enhancement; 754—Quentin N. Burdick Program for Rural Interdisciplinary Training; 755—Allied Health and Other Disciplines; 756—Mental and Behavioral Health Education and Training, and 759—

Program for Education and Training in Pain Care.

The members of the ACICBL will resume their discussion of the legislatively mandated 15th Annual Report to the Secretary of Health and Human Services and Congress. The Committee members will continue to review, discuss, and make recommendations for programs under title VII, part D. The members will hear presentations on allied health, podiatry, chiropractic, pain care management, the budget process, primary care workforce reports, healthcare practice redesign, interprofessional accreditation standards, and performance measurement.

Agenda: Healthcare practice redesign initiatives, such as the Patient-Centered Medical Home Model or the Planned Care Model, are emerging approaches to improve the quality of primary health care delivery. These models are comprehensive, multifaceted, and seek to provide high-quality care and continuity while involving patients, communities, health care teams, and policy makers. The members of the ACICBL will review (a) current issues related to healthcare practice redesign, (b) the implications of practice redesign on health professions education in relation to title VII, part D programs, and (c) accreditation standards for the disciplines that have incorporated interprofessional education into their accreditation standards and the effect this has had on practice. Committee discussion questions include:

- How will changing the scope of practice of health professionals affect title VII, part D programming?
- What statutory changes are needed to align with healthcare practice redesign?
- What measures are needed for title VII, part D programs to have an impact on outcomes and quality?

The official agenda will be available 2 days prior to the meeting on the HRSA Web site at: *http://www.hrsa.gov/advisorycommittees/bhpradvisory/acicbl/index.html.* Agenda items are subject to change as priorities dictate.

Public Comment: Requests to make oral comments or provide written comments to the ACICBL should be sent to Dr. Joan Weiss, Designated Federal Official, using the address and phone number below. Individuals who plan to participate on the conference call or webinar should notify Dr. Weiss at least 3 days prior to the meeting, using the address and phone number below. Members of the public will have the opportunity to provide comments. Interested parties should refer to the meeting subject as the HRSA Advisory Committee on Interdisciplinary, Community-Based Linkages.

The conference call-in number is 877–960–9066. The passcode is: 5919914.

The webinar link is: *https://hrsa.connectsolutions.com/acicblapril22_23/.*

FOR FURTHER INFORMATION CONTACT: Anyone requesting information regarding the ACICBL should contact Dr. Joan Weiss, Designated Federal Official within the Bureau of Health Workforce, Health Resources and Services Administration, in one of three ways: (1) Send a request to the following address: Dr. Joan Weiss, Designated Federal Official, Bureau of Health Workforce, Health Resources and Services Administration, Parklawn Building, Room 12C–05, 5600 Fishers Lane, Rockville, Maryland 20857; (2) call (301) 443–0430; or (3) send an email to *jweiss@hrsa.gov.*

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–07154 Filed 3–27–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Establishment of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria and Solicitation of Nominations for Appointment to the Council Membership

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services (HHS) announces establishment of the Advisory Council. The Advisory Council will provide advice, information, and recommendations to the Secretary regarding programs and policies intended to support and evaluate the implementation of Executive Order 13676, including the National Strategy for Combating Antibiotic-Resistant Bacteria (Strategy) and the National Action Plan for Combating Antibiotic-Resistant Bacteria (Action Plan).

This notice also will serve to announce that HHS is seeking nominations of individuals who are interested in being considered for appointment to the Advisory Council. Resumes or curricula vitae from qualified individuals who wish to be considered for appointment as a member of the Advisory Council are currently being accepted.

DATES: Nominations must be received no later than close business April 29, 2015.

ADDRESSES: All nominations should be sent to: Bruce Gellin, M.D., M.P.H., Deputy Assistant Secretary for Health; Office of the Assistant Secretary for Health; Department of Health and Human Services; 200 Independence Avenue SW., Room 715H; Washington, DC 20201. Nomination materials, including attachments, also may be submitted electronically to *CARB@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Bruce Gellin, M.D., M.P.H., Deputy Assistant Secretary for Health; Office of the Assistant Secretary for Health; Department of Health and Human Services; Telephone: (202) 260–6638; Fax: (202) 690–4631; Email address: *CARB@hhs.gov.* The Advisory Council charter may be accessed online at *http://www.hhs.gov/ash/carb.* The charter includes detailed information about the Advisory Council's purpose, function, and structure.

SUPPLEMENTARY INFORMATION: The rise of antibiotic-resistant bacteria represents a serious threat to public health and the economy. Detecting, preventing, and controlling antibiotic resistance requires a strategic, coordinated, and sustained effort. The federal government will work domestically and internationally to detect, prevent, and control illness and death related to antibiotic-resistant infections by implementing measures that reduce the emergence and spread of antibiotic-resistant bacteria and help ensure the continued availability of effective therapeutics for the treatment of bacterial infections.

Under Executive Order 13676, the Secretary of Health and Human Services (the Secretary) is directed to establish the Advisory Council in consultation with the Secretaries of Defense and Agriculture. The Advisory Council will provide advice and recommendations to the Secretary regarding programs and policies to support and evaluate the implementation of Executive Order 13676, including the National Strategy

Authority: Executive Order 13676, dated September 18, 2014, authorizes establishment of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council). The Advisory Council will be governed by provisions of the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

for Combating Antibiotic-Resistant Bacteria (Strategy) and the National Action Plan for Combating Antibiotic-Resistant Bacteria (Action Plan). On March 24, 2015, the Secretary approved for the Advisory Council to be established. The charter for the Advisory Council was filed with the appropriate Congressional committees and the Library of Congress on the same date. The Advisory Council has been established as a non-discretionary federal advisory committee.

Objectives and Scope of Activities. The Advisory Council will provide advice, information, and recommendations to the Secretary regarding programs and policies intended to support and evaluate the implementation of Executive Order 13676, including the Strategy and Action Plan. The Advisory Council will function solely for advisory purposes.

Membership and Designation. The Advisory Council will consist of not more than 30 members, including the voting and non-voting members and Chair and Vice Chair. The members will be appointed or designated by the Secretary, who will designate the Chair and Vice Chair from among the voting members of the Advisory Council.

Voting Members. There will be public voting members selected from individuals who are engaged in research on, or implementation of, interventions regarding efforts to preserve the effectiveness of antibiotics by optimizing their use; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial infections; prevent the transmission of antibiotic-resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research on new treatments for bacterial infections; develop alternatives to antibiotics for agricultural purposes; maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and improve international coordination of efforts to combat antibiotic resistance.

The public voting members will represent balanced points of view from human biomedical, public health, and agricultural fields to include surveillance of antibiotic-resistant infections, prevention and/or interruptions of the spread of antibiotic-resistant threats, or development of rapid diagnostics and novel treatments. The public voting members may be physicians, veterinarians, epidemiologists, microbiologists, or other health care professionals (*e.g.,* nurses, pharmacists, others); individuals who have expertise and experience as consumer or patient advocates concerned with antibiotic resistance, or in the fields of agriculture and pharmaceuticals; and they also may be from State or local health agencies or public health organizations. All public voting members will be classified as special Government employees (SGEs).

Ex-officio Members (non-voting). The Advisory Council will include members selected to represent various federal agencies, including HHS, DoD, and USDA, that are involved in the development, testing, licensing, production, procurement, distribution, and/or use of antibiotics and/or antibiotic research. The federal *ex-officio* members shall possess the knowledge, skills, experience, and expertise necessary to generate informed and intelligent recommendations with respect to the issues mandated by Executive Order 13676. Federal agencies will be invited to participate as non-voting *ex-officio* members of the Advisory Council, as it is deemed necessary by the Secretary, in consultation with the Secretaries of Defense and Agriculture, to accomplish the mission the Advisory Council.

Liaison Representatives (non-voting). The Advisory Council structure also may include non-voting liaison representatives from organizations and/or interest groups that have involvement in the development, testing, licensing, production, procurement, distribution, and/or use of antibiotics and/or antibiotic research. Organizations will be invited to participate as non-voting liaison representatives as it is deemed necessary by the Secretary or designee to accomplish the established mission of the Advisory Council.

The public voting and non-voting liaison representative members will be appointed to serve for overlapping terms of up to four years. The Chair and Vice Chair will be appointed to serve for three years, unless otherwise specified.

The public voting members are authorized to receive per diem and reimbursement for travel expenses when attending meetings of the Advisory Council, as authorized by Section 5703, Title 5 U.S.C., as amended for persons employed intermittently in Government service. Individuals who are appointed to serve as non-voting liaison representative members also may be allowed to receive per diem and reimbursement for any applicable expenses for travel that is performed to attend meetings of the Advisory Council in accordance with Federal travel regulations.

Estimated Number and Frequency of Meetings. The Advisory Council will meet, at a minimum, two times per fiscal year depending on the availability of funds. Meetings will be open to the public, except as determined otherwise by the Secretary or other official to whom the authority has been delegated in accordance with guidelines under Government in the Sunshine Act, 5 U.S.C. 552b(c).

Nominations: Nominations, including self-nominations, of individuals who have the specified expertise and knowledge will be considered for appointment as public voting and/or non-voting members of the Advisory Council. A nomination should include, at a minimum, the following for each nominee: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.,* the desired member category and specific attributes which qualify the nominee to be considered for appointment as a public voting and/or non-voting member of the Advisory Council), and a statement from the nominee (including designated representatives of organizations and/or interest groups) that indicates that the individual is willing to serve as a member of the Advisory Council, if selected; (2) the nominator's name, address, and daytime telephone number, and the address, telephone number, and email address of the individual being nominated; and (3) a current copy of the nominee's curriculum vitae or resume, which should be limited to no more than 10 pages.

Every effort will be made to ensure that the Advisory Council is a diverse group of individuals with representation from various geographic locations, racial and ethnic minorities, all genders, and persons living with disabilities.

Individuals being considered for appointment as public voting members will be required to complete and submit a report of their financial holdings. An ethics review must be conducted to ensure that individuals appointed as public voting members of the Advisory Council are not involved in any activity that may pose a potential conflict of interest for the official duties that are to be performed. This is a federal ethics requirement that must be satisfied upon entering the position and annually throughout the established term of appointment on the Advisory Council.

Dated: March 24, 2015.

Sylvia M. Burwell,

Secretary of Health and Human Services.

[FR Doc. 2015–07235 Filed 3–27–15; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–29, CMS–10221 and CMS–R–263]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by April 29, 2015.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR* Email: *OIRA_submission@omb.eop.gov*.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*
3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Verification of Clinic Data—Rural Health Clinic Form and Supporting Regulations; *Use:* The form is utilized as an application to be completed by suppliers of Rural Health Clinic (RHC) services requesting participation in the Medicare program. This form initiates the process of obtaining a decision as to whether the conditions for certification are met as a supplier of RHC services. It also promotes data reduction or introduction to and retrieval from the Automated Survey Process Environment (ASPEN) and related survey and certification databases by the CMS Regional Offices. Should any question arise regarding the structure of the organization, this information is readily available. *Form Number:* CMS–29 (OMB control number 0938–0074); *Frequency:* Occasionally (initially and then every six years); *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 900; *Total Annual Responses:* 900; *Total Annual Hours:* 150. (For policy questions regarding this collection contact Shonté Carter at 410–786–3532.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Site Investigation for Independent Diagnostic Testing Facilities (IDTFs); *Use:* We enroll Independent Diagnostic Testing Facilities (IDTFs) into the Medicare program via a uniform application, the CMS 855B. Implementation of enhanced procedures for verifying the enrollment information has improved the enrollment process as well as identified and prevented fraudulent IDTFs from entering the Medicare program. As part of this process, verification of compliance with IDTF performance standards is necessary. The primary function of the site investigation form for IDTFs is to provide a standardized, uniform tool to gather information from an IDTF that tells us whether it meets certain standards to be a IDTF (as found in 42 CFR 410.33(g)) and where it practices or renders its services. The site investigation form has been used in the past to aid in verifying compliance with the required performance standards found in 42 CFR 410.33(g). No revisions have been made to this form since the last submission for OMB approval. *Form Number:* CMS–10221 (OMB Control Number: 0938–1029); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 900; *Total Annual Responses:* 900; *Total Annual Hours:* 1,800. (For policy questions regarding this collection contact Kim McPhillips at 410–786–5374).

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Site Investigation for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS); *Use:* We enroll suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) into the Medicare program via a uniform application, the CMS 855S. Implementation of enhanced procedures for verifying the enrollment information has improved the enrollment process as well as identified and prevented fraudulent DMEPOS suppliers from entering the Medicare program. As part of this process, verification of compliance with supplier standards is necessary. The primary function of the site investigation form is to provide a standardized, uniform tool to gather information from a DMEPOS

supplier that tells us whether it meets certain qualifications to be a DMEPOS supplier (as found in 42 CFR 424.57(c)) and where it practices or renders its services. The site investigation form has been used in the past to aid in verifying compliance with the required supplier standards found in 42 CFR 424.57(c). No revisions have been made to this form since the last submission for OMB approval. *Form Number:* CMS–R–263 (OMB Control Number: 0938–0749); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 30,000; *Total Annual Responses:* 30,000; *Total Annual Hours:* 15,000. (For policy questions regarding this collection contact Kim McPhillips at 410–786–5374).

Dated: March 25, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–07219 Filed 3–27–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10558 and CMS–10463]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by May 29, 2015.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10558 Information Collection for Machine Readable Data for Provider Network and Prescription Formulary Content for FFM QHPs

CMS–10463 Cooperative Agreement to Support Navigators in Federally-Facilitated and State Partnership Exchanges

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Title of Information Collection:* Information Collection for Machine Readable Data for Provider Network and Prescription Formulary Content for FFM QHPs; *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Use:* For plan years beginning on or after January 1, 2016, qualified health plan (QHP) issuers must make available provider and formulary data in a machine-readable format. As required by the final rule Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016 (CMS–9944–F), 80 **Federal Register** 10750 February 27, 2015, QHP issuers in the Federally-facilitated Marketplaces (FFMs) are required to publish information regarding their formulary drug lists and provider directories on its Web site in an HHS-specified format, in a format and at times determined by HHS. *Form Number:* CMS–10558 (0938-New); *Frequency:* Monthly; *Affected Public:* Private Sector (Business or other For-profits and Not-for-Profit institutions); *Number of Respondents:* 475; *Number of Responses:* 36; *Total Annual Hours:* 79,800. (For questions regarding this collection, contact Lisa-Ann Bailey at (301) 492- 4169.)

2. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Cooperative Agreement to Support Navigators in Federally-facilitated and State Partnership Exchanges; *Use:* Section 1311(i) of the Affordable Care Act requires Exchanges to establish a Navigator grant program as part of its function to provide consumers with assistance when they need it. Navigators will assist consumers by providing education about and facilitating selection of qualified health plans

(QHPs) within Exchanges, as well as other required duties. Section 1311(i) requires that an Exchange operating as of January 1, 2014, must establish a Navigator Program under which it awards grants to eligible individuals or entities who satisfy the requirements to be Exchange Navigators. In States with a Federally-facilitated Marketplace (FFM) or State Partnership Marketplace (SPM), we will be awarding these grants. Navigator awardees must provide weekly, monthly, quarterly, and annual progress reports to us on the activities performed during the grant period and any sub-awardees receiving funds. *Form Number:* CMS–10463 (OMB Control Number: 0938–1215); *Frequency:* Annually; Quarterly; Monthly; Weekly; *Affected Public:* Private sector (For-profit and Not-for-profit institutions); *Number of Respondents:* 102; *Total Annual Responses:* 7,038; *Total Annual Hours:* 29,226. (For policy questions regarding this collection, contact Julia Dreier at 301–492–4123.)

Dated: March 24, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–07089 Filed 3–27–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HOMELAND SECURITY

United States Immigration and Customs Enforcement

[File No. I–352, Immigration Bond; OMB Control No. 1653–0022]

Agency Information Collection Activities: Extension, With Change, of an Existing Information Collection; Comment Request

ACTION: 60-Day notice of information collection.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (ICE), is submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until May 29, 2015.

Written comments and suggestions regarding items contained in this notice, and especially with regard to the estimated public burden and associated response time should be directed to the Department of Homeland Security (DHS), Scott Elmore, Forms Management, U.S. Immigration and Customs Enforcement, 801 I Street NW., Stop 5800, Washington, DC 20536.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

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

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

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

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

Overview of This Information Collection

(1) *Type of Information Collection:* Extension, with change, of an existing information collection.

(2) *Title of the Form/Collection:* Immigration Bond.

(3) *Agency form number, if any and the applicable component of the Department of Homeland Security sponsoring the collection:* I–352, U.S. Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individual or Households; Business or other for-profit. The data collected on this collection instrument is used by ICE to ensure that the person or company posting the bond is aware of the duties and responsibilities associated with the bond. The collection instrument serves the purpose of instruction in the completion of the form, together with an explanation of the terms and conditions of the bond. Sureties have the capability of accessing, completing and submitting a bond electronically through ICE's eBonds system which encompasses the I–352, while individuals are still required to complete the bond form manually.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 25,000 responses at 30 minutes (.50 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 12,500 annual burden hours.

Comments and/or questions; requests for a copy of the proposed information collection instrument, with instructions; or inquiries for additional information should be directed to: Scott Elmore, Forms Management, U.S. Immigration and Customs Enforcement, 801 I Street NW., Stop 5800, Washington, DC 20536.

Dated: March 24, 2015.

Scott Elmore,

Forms Management, U.S. Immigration and Customs Enforcement, Department of Homeland Security.

[FR Doc. 2015–07131 Filed 3–27–15; 8:45 am]

BILLING CODE 9111–28–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0123]

Agency Information Collection Activities: Application for Provisional Unlawful Presence Waiver of Inadmissibility, Form I–601A; Revision of a Currently Approved Collection

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection notice was previously published in the **Federal Register** on June 27, 2014, at 79 FR 36543, allowing for a 60-day public comment period. USCIS received two comments in connection with the 60-day notice.

DATES: The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until April 29, 2015. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be directed to the OMB USCIS Desk Officer

via email at *oira_submission@omb.eop.gov.* Comments may also be submitted via fax at (202) 395–5806. All submissions received must include the agency name and the OMB Control Number 1615–0123.

You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make. For additional information please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: If you need a copy of the information collection instrument with instructions, or additional information, please visit the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2012–0003 in the search box. We may also be contacted at: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Laura Dawkins, Chief, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, Telephone number 202–272–8377.

SUPPLEMENTARY INFORMATION:

Comments

Note: The address listed in this notice should only be used to submit comments concerning this information collection. Please do not submit requests for individual case status inquiries to this address. If you are seeking information about the status of your individual case, please check ''My Case Status'' online at: *https://egov.uscis.gov/cris/Dashboard.do,* or call the USCIS National Customer Service Center at 1–800–375–5283.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

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

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

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

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

Overview of This Information Collection

(1) *Type of Information Collection Request:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application for Provisional Unlawful Presence Waiver of Inadmissibility.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–601A; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households: Individuals who are immediate relatives of U.S. citizens and who are applying from within the United States for a waiver of inadmissibility under INA section 212(a)(9)(B)(v) prior to obtaining an immigrant visa abroad.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

—Form I–601A: 35,000 at 1.5 hours.
—Biometrics: 35,000 at 1.17 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 93,450 total annual burden hours.

Dated: March 25, 2015.

Laura Dawkins,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2015–07225 Filed 3–27–15; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2015–0001; Internal Agency Docket No. FEMA–B–1476]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Title 44, Part 65 of the Code of Federal Regulations (44 CFR part 65). The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will become effective on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map

repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: February 23, 2015.

Roy E. Wright,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Delaware: New Castle.	Unincorporated areas of New Castle County (14–03–0976P).	The Honorable Thomas P. Gordon, New Castle County Executive, 87 Reads Way, New Castle, DE 19720.	New Castle County Government Center, 87 Reads Way, New Castle, DE 19720.	*http://www.msc.fema.gov/lomc*	Jan. 30, 2015	105085
Pennsylvania:						
Allegheny	City of Pittsburgh (14–03–1501P).	The Honorable William Peduto, Mayor, City of Pittsburgh, 512 City County Building, 414 Grant Street, Pittsburgh, PA 15219.	Department of City Planning, 200 Ross Street, 4th Floor, Pittsburgh, PA 15219.	*http://www.msc.fema.gov/lomc*	Jan. 29, 2015	420063
Bucks	Borough of New Hope (14–03–1346P).	Mr. John Burke, Manager, Borough of New Hope, 123 New Street, New Hope, PA 18938.	Borough Hall, 123 New Street, New Hope, PA 18938.	*http://www.msc.fema.gov/lomc*	Mar. 17, 2015	420195
Texas:						
Bexar	City of San Antonio (14–06–3621P).	The Honorable Ivy R. Taylor, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Department of Public Works, Storm Water Engineering, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78204.	*http://www.msc.fema.gov/lomc*	Feb. 12, 2015	480045
Bexar	Unincorporated areas of Bexar County, (14–06–3621P).	The Honorable Nelson W. Wolff, Bexar County Judge, Paul Elizondo Tower, 101 West Nueva Street, 10th Floor, San Antonio, TX 78205.	Bexar County Public Works Department, 233 North Pecos-La Trinidad Street, Suite 420, San Antonio, TX 78207.	*http://www.msc.fema.gov/lomc*	Feb. 12, 2015	480035
Dallas	City of Farmers Branch, (14–06–2597P).	The Honorable Bob Phelps, Mayor, City of Farmers Branch, 13000 William Dodson Parkway, Farmers Branch, TX 75234.	City Hall, 13000 William Dodson Parkway, Farmers Branch, TX 75234.	*http://www.msc.fema.gov/lomc*	Feb. 2, 2015	480174
Dallas	Town of Highland Park, (14–06–0617P).	The Honorable Joel T. Williams, III, Mayor, Town of Highland Park, 4700 Drexel Drive, Highland Park, Texas 75205.	Public Works Department, 4700 Drexel Drive, Highland Park, Texas 75205.	*http://www.msc.fema.gov/lomc*	Feb. 13, 2015	480178
Ector	City of Odessa, (14–06–2873P).	The Honorable David Turner, Mayor, City of Odessa, P.O. Box 4398, Odessa, TX 79760.	City Hall, 411 West 8th Avenue, Odessa, TX 79760.	*http://www.msc.fema.gov/lomc*	Feb. 10, 2015	480206
Ellis	City of Waxahachie, (13–06–4294P).	The Honorable Kevin Strength, Mayor, City of Waxahachie, 401 South Rogers Street, Waxahachie, TX 75165.	401 South Rogers Street, Waxahachie, TX 75165.	*http://www.msc.fema.gov/lomc*	Jan. 29, 2015	480211
Grayson	Town of Gunter, (14–06–0033P).	The Honorable Don Anderson, Mayor, Town of Gunter, P.O. Box 349, Gunter, TX 75058.	Town Hall, 418 West Main Street, Gunter, TX 75058.	*http://www.msc.fema.gov/lomc*	Feb. 3, 2015	480832

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Grayson	Unincorporated areas of Grayson County, (14–06–0033P).	The Honorable Drue Bynum, Grayson County Judge, 100 West Houston Street, Sherman, TX 75090.	Grayson County Courthouse, 100 West Houston Street, Sherman, TX 75090.	*http://www.msc.fema.gov/lomc*	Feb. 3, 2015	480829
Lampasas	Unincorporated areas of Lampasas County. (14–06–1364P).	The Honorable Wayne L. Boultinghouse, Lampasas County Judge, P.O. Box 231, Lampasas, TX 76550.	Lampasas County Courthouse, County Judge's Office, 501 East 4th Street, Lampasas, TX 76550.	*http://www.msc.fema.gov/lomc*	Dec. 8, 2014	480899

[FR Doc. 2015–07147 Filed 3–27–15; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0024]

Agency Information Collection Activities: Entry/Immediate Delivery Application and ACE Cargo Release

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Entry/Immediate Delivery Application (Forms 3461 and 3461 ALT) and ACE Cargo Release. CBP is proposing that this information collection be extended with a change to the burden hours. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before April 29, 2015 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** (80 FR 3973) on January 26, 2015, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10. CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3507). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden, including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

Title: Entry/Immediate Delivery Application and ACE Cargo Release.

OMB Number: 1651–0024.

Form Number: 3461 and 3461 ALT.

Abstract: All items imported into the United States are subject to examination before entering the commerce of the United States. There are two procedures available to effect the release of imported merchandise, including ''entry'' pursuant to 19 U.S.C. 1484, and ''immediate delivery'' pursuant to 19 U.S.C. 1448(b). Under both procedures, CBP Forms 3461, Entry/Immediate Delivery, and 3461 ALT are the source documents in the packages presented to Customs and Border Protection (CBP). The information collected on CBP Forms 3461 and 3461 ALT allow CBP officers to verify that the information regarding the consignee and shipment is correct and that a bond is on file with CBP. CBP also uses these forms to close out the manifest and to establish the obligation to pay estimated duties in the time period prescribed by law or regulation. CBP Form 3461 is also a delivery authorization document and is given to the importing carrier to authorize the release of the merchandise.

CBP Forms 3461 and 3461 ALT are provided for by 19 CFR parts 141 and 142. These forms and instructions for Form 3461 are accessible at: *http://www.cbp.gov/newsroom/publications/forms.*

ACE Cargo Release is a program for ACE entry summary filers in which importers or brokers may file Simplified Entry data in lieu of filing the CBP Form 3461. This data consists of 12 required elements: Importer of record; buyer name and address; buyer employer identification number (consignee number), seller name and address; manufacturer/supplier name and address; Harmonized Tariff Schedule 10-digit number; country of origin; bill of lading; house air waybill number; bill of lading issuer code; entry number; entry type; and estimated shipment value. Three optional data elements are the container stuffing location; consolidator name and address, and ship to party name and address. The data collected under the ACE Cargo Release program is intended to reduce transaction costs, expedite cargo release, and enhance cargo security. ACE Cargo Release filing minimizes the redundancy of data submitted by the filer to CBP through receiving carrier data from the carrier. This design allows the participants to file earlier in the transportation flow. Guidance on using ACE Cargo Release may be found at *http://www.cbp.gov/trade/ace/features.*

Current Actions: This submission is being made to extend the expiration date with a change in the burden hours resulting from the transition from Form 3461 to ACE Cargo Release. There are no changes to the information collected.

Type of Review: Extension (with change).

Affected Public: Businesses.

CBP Form 3461

Estimated Number of Respondents: 3,014.

Estimated Number of Responses per Respondent: 1,410.

Estimated Total Annual Responses: 4,249,740.

Estimated Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 1,062,435.

CBP Form 3461 ALT

Estimated Number of Respondents: 6,795.

Estimated Number of Responses per Respondent: 1,390.

Estimated Total Annual Responses: 9,444,069.

Estimated Time per Response: 3 minutes.

Estimated Total Annual Burden Hours: 472,203.

ACE Cargo Release

Estimated Number of Respondents: 3,015.

Estimated Number of Responses per Respondent: 1,410.

Estimated Total Annual Responses: 4,251,150.

Estimated Time per Response: 10 minutes.

Estimated Total Annual Burden Hours: 705,691.

Dated: March 25, 2015.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2015–07196 Filed 3–27–15; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2014–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The effective date of March 16, 2015 which has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *www.msc.fema.gov* by the effective date indicated above.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: February 26, 2015.

Roy E. Wright,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Sussex County, Delaware, and Incorporated Areas	
Docket No.: FEMA–B–1352	
City of Lewes	City Hall, 114 East 3rd Street, Lewes, DE 19958.
City of Milford	Planning Department, 201 South Walnut Street, Milford, DE 19963.
City of Rehoboth Beach	Building and Licensing Department, 306 Rehoboth Avenue, Rehoboth Beach, DE 19971.
City of Seaford	City Hall, 414 High Street, Seaford, DE 19973.
Town of Bethany Beach	Building Inspector's Office, 214 Garfield Parkway, Bethany Beach, DE 19930.
Town of Bethel	The Community House, 7769 Main Street, Bethel, DE 19931.
Town of Blades	Town Hall, 20 West Fourth Street, Blades, DE 19973.
Town of Bridgeville	Town Hall, 101 North Main Street, Bridgeville, DE 19933.

Community	Community map repository address
Town of Dagsboro	Town Hall, 33134 Main Street, Dagsboro, DE 19939.
Town of Dewey Beach	Town Hall, 105 Rodney Avenue, Dewey Beach, DE 19971.
Town of Fenwick Island	Building Department, 800 Coastal Highway, Fenwick Island, DE 19944.
Town of Greenwood	Town Hall, 100 West Market Street, Greenwood, DE 19950.
Town of Henlopen Acres	Henlopen Acres Town Hall, 104 Tidewater Road, Rehoboth Beach, DE 19971.
Town of Laurel	Code Enforcement Office, 201 Mechanic Street, Laurel, DE 19956.
Town of Millsboro	Town Center, 322 Wilson Highway, Millsboro, DE 19966.
Town of Millville	Town Hall, 36404 Club House Road, Millville, DE 19967.
Town of Milton	Town Hall, 115 Federal Street, Milton, DE 19968.
Town of Ocean View	Wallace A. Melson Municipal Building, 201 Central Avenue, 2nd Floor, Ocean View, DE 19970.
Town of Slaughter Beach	Town Office, Memorial Fire Company Station 89, 2nd Floor, 359 Bay Avenue, Slaughter Beach, DE 19963.
Unincorporated Areas of Sussex County	Sussex County Planning and Zoning Department, 2 The Circle, Georgetown, DE 19947.

[FR Doc. 2015–07148 Filed 3–27–15; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

Outer Continental Shelf, Gulf of Mexico, Oil and Gas Lease Sales, Western Planning Area Lease Sale 248 MMAA 104000

AGENCY: Bureau of Ocean Energy Management (BOEM), Interior.

ACTION: Notice of Intent to Prepare a Supplemental Environmental Impact Statement and Announcement of Scoping Meetings and Comment Period for Proposed Gulf of Mexico Outer Continental Shelf Oil and Gas Western Planning Area Lease Sale 248.

SUMMARY: Consistent with the regulations implementing the National Environmental Policy Act, as amended (42 U.S.C. 4321 *et seq.*) (NEPA), BOEM is announcing its intent to prepare a Supplemental Environmental Impact Statement (EIS) for proposed Western Planning Area (WPA) Lease Sale 248 in the Gulf of Mexico (WPA 248 Supplemental EIS). The WPA 248 Supplemental EIS will update the environmental and socioeconomic analyses in the *Gulf of Mexico OCS Oil and Gas Lease Sales: 2012–2017; Western Planning Area Lease Sales 229, 233, 238, 246, and 248; Central Planning Area Lease Sales 227, 231, 235, 241, and 247, Final Environmental Impact Statement* (2012–2017 WPA/CPA Multisale EIS; OCS EIS/EA BOEM 2012–019); *Gulf of Mexico OCS Oil and Gas Lease Sales: 2013–2014; Western Planning Area Lease Sale 233; Central Planning Area Lease Sale 231, Final Supplemental Environmental Impact Statement* (WPA 233/CPA 231 Supplemental EIS; OCS EIS/EA BOEM 2013–0118); *Gulf of Mexico OCS Oil and Gas Lease Sales: 2014–2016; Western Planning Area Lease Sales 238, 246, and 248, Final Supplemental Environmental Impact Statement* (WPA 238, 246, and 248 Supplemental EIS; OCS EIS/EA BOEM 2014–009); and *Gulf of Mexico OCS Oil and Gas Lease Sales: 2015 and 2016; Western Planning Area Lease Sales 246 and 248, Final Supplemental Environmental Impact Statement* (WPA 246 and 248 Supplemental EIS; OCS EIS/EA BOEM 2015–008).

The WPA 248 Supplemental EIS will supplement the NEPA documents cited above for the proposed lease sale in order to consider new circumstances and information arising from, among other things, the *Deepwater Horizon* explosion, oil spill, and response. It will focus on updating the baseline conditions and any new information on the potential environmental effects of oil and natural gas leasing, exploration, development, and production in the WPA identified through the Area Identification procedure as the proposed lease sale area. In addition to the no action alternative (*i.e.,* canceling the proposed lease sale), other alternatives may be considered for the proposed WPA lease sale, such as deferring certain areas from the proposed lease sale area.

DATES: Comments should be submitted by April 29, 2015 to the address specified above.

FOR FURTHER INFORMATION CONTACT: For information on the WPA 248 Supplemental EIS, the submission of comments, or BOEM's policies associated with this notice, please contact: Mr. Gary D. Goeke, Chief, Environmental Assessment Section, Office of Environment (GM 623E), Bureau of Ocean Energy Management, Gulf of Mexico OCS Region, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394, telephone 504–736–3233.

SUPPLEMENTARY INFORMATION: On August 27, 2012, the Secretary of the Interior approved as final the *Proposed Final OCS Oil & Gas Leasing Program: 2012–2017* (Five-Year Program). This Supplemental EIS will consider the one remaining WPA lease sale for this 2012–2017 Five-Year Program. The proposed WPA lease sale area encompasses virtually all of the WPA's 28.58 million acres, with the exception of whole and partial blocks within the boundary of the Flower Garden Banks National Marine Sanctuary.

This **Federal Register** notice is not an announcement to hold the proposed lease sale, but it is a continuation of information gathering and is published early in the environmental review process in furtherance of the goals of NEPA. Once the NEPA process and WPA 248 Supplemental EIS is completed, the WPA 248 Supplemental EIS content will be summarized in presale documentation prepared during the decisionmaking process for WPA Lease Sale 248. If, after completion of the WPA 248 Supplemental EIS, the Department of the Interior's Assistant Secretary for Land and Minerals Management decides to hold the lease sale, then the lease sale area identified in the final Notice of Sale may exclude or defer certain lease blocks from the area offered. However, for purposes of the WPA 248 Supplemental EIS and to adequately assess the potential impacts of an areawide lease sale, BOEM will consider all unleased blocks that may be offered in proposed WPA Lease Sale 248.

Scoping Process: This Notice of Intent (NOI) serves to announce the scoping process for identifying issues and alternatives to consider in the WPA 248 Supplemental EIS. Throughout the scoping process, Federal, State, Tribal,

and local governments and the general public have the opportunity to help BOEM determine significant resources and issues, impacting factors, reasonable alternatives, and potential mitigating measures to be analyzed in the WPA 248 Supplemental EIS and to provide additional information. BOEM will also use the NEPA commenting process to initiate the Section 106 consultation process of the National Historic Preservation Act (16 U.S.C. 470f), as provided for in 36 CFR 800.2(d)(3).

Pursuant to the regulations implementing the procedural provisions of NEPA (42 U.S.C. 4321 *et seq.*), BOEM will hold public scoping meetings in Texas and Louisiana on the WPA 248 Supplemental EIS. The purpose of these meetings is to solicit comments on the scope of the WPA 248 Supplemental EIS. BOEM's scoping meetings will be held at the following places and times:

- Houston, Texas: Tuesday, April 14, 2015, Houston Airport Marriott at George Bush Intercontinental, 18700 John F. Kennedy Boulevard, Houston, Texas 77032, one meeting beginning at 1:00 p.m. CDT; and
- New Orleans, Louisiana: Thursday, April 16, 2015, Bureau of Ocean Energy Management, Gulf of Mexico OCS Region, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123, one meeting beginning at 1:00 p.m. CDT.

Cooperating Agency: BOEM invites other Federal, State, Tribal, and local governments to consider becoming cooperating agencies in the preparation of the WPA 248 Supplemental EIS. We invite qualified government entities to inquire about cooperating agency status for the WPA 248 Supplemental EIS. Following the guidelines from the Council on Environmental Quality (CEQ), qualified agencies and governments are those with ''jurisdiction by law or special expertise.'' Potential cooperating agencies should consider their authority and capacity to assume the responsibilities of a cooperating agency, and remember that an agency's role in the environmental analysis neither enlarges nor diminishes the final decisionmaking authority of any other agency involved in the NEPA process. Upon request, BOEM will provide potential cooperating agencies with a written summary of ground rules for cooperating agencies, including time schedules and critical action dates, milestones, responsibilities, scope and detail of cooperating agencies' contributions, and availability of predecisional information. BOEM anticipates this summary will form the basis of a Memorandum of Agreement between BOEM and any cooperating agency. Agencies should also consider the ''Factors for Determining Cooperating Agency Status'' in Attachment 1 to CEQ's January 30, 2002, Memorandum for the Heads of Federal Agencies: *Cooperating Agencies in Implementing the Procedural Requirements of the National Environmental Policy Act.* These documents are available at the following locations on the Internet: *http://ceq.hss.doe.gov/nepa/regs/cooperating/.html;* and *http://ceq.hss.doe.gov/nepa/regs/cooperating/.html.*

BOEM, as the lead agency, will not provide financial assistance to cooperating agencies. Even if an organization is not a cooperating agency, opportunities will exist to provide information and comments to BOEM during the normal public input stages of the NEPA/EIS process. For further information about cooperating agencies, please contact Mr. Gary D. Goeke at 504–736–3233.

Comments: All interested parties, including Federal, State, Tribal, and local governments, and other interested parties, may submit written comments on the scope of the WPA 248 Supplemental EIS, significant issues that should be addressed, alternatives that should be considered, potential mitigating measures, and the types of oil and gas activities of interest in the proposed WPA 248 lease sale area.

Written scoping comments may be submitted in one of the following ways:

1. In an envelope labeled ''Scoping Comments for the WPA 248 Supplemental EIS'' and mailed (or hand delivered) to Mr. Gary D. Goeke, Chief, Environmental Assessment Section, Office of Environment (GM 623E), Bureau of Ocean Energy Management, Gulf of Mexico OCS Region, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394;
2. Through the regulations.gov web portal: Navigate to *http://www.regulations.gov* and search for ''Oil and Gas Lease Sales: Gulf of Mexico, Outer Continental Shelf; Western Planning Area Lease Sale 248'' (Note: It is important to include the quotation marks in your search terms). Click on the ''Comment Now!'' button to the right of the document link. Enter your information and comment, then click ''Submit''; or
3. Through BOEM's email address: *wpa248@boem.gov.*

Petitions, although accepted, do not generally provide useful information to assist in the development of alternatives, resources, and issues to be analyzed, or impacting factors. BOEM does not consider anonymous comments; please include your name and address as part of your submittal. BOEM makes all comments, including the names and addresses of respondents, available for public review during regular business hours. Individual respondents may request that BOEM withhold their names and/or addresses from the public record; however, BOEM cannot guarantee that we will be able to do so. If you wish your name and/or address to be withheld, you must state your preference prominently at the beginning of your comment. All submissions from organizations or businesses and from individuals identifying themselves as representatives or officials of organizations or businesses will be made available for public inspection in their entirety.

Authority: This NOI is published pursuant to the regulations (40 CFR 1501. 7) implementing the provisions of NEPA.

Dated: March 25, 2015.

Abigail Ross Hopper,

Director, Bureau of Ocean Energy Management.

[FR Doc. 2015–07325 Filed 3–27–15; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–IA–2015–N061; FXIA16710900000–156–FF09A30000]

Endangered Species; Marine Mammals; Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species, marine mammals, or both. With some exceptions, the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA) prohibit activities with listed species unless Federal authorization is acquired that allows such activities.

DATES: We must receive comments or requests for documents on or before April 29, 2015. We must receive requests for marine mammal permit public hearings, in writing, at the address shown in the **ADDRESSES** section by April 29, 2015.

ADDRESSES: Brenda Tapia, U.S. Fish and Wildlife Service, Division of Management Authority, Branch of Permits, MS: IA, 5275 Leesburg Pike,

Falls Church, VA 22041; fax (703) 358–2281; or email *DMAFR@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358–2104 (telephone); (703) 358–2281 (fax); *DMAFR@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I request copies of applications or comment on submitted applications?

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **ADDRESSES**. Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an email or address not listed under **ADDRESSES**. If you provide an email address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

B. May I review comments submitted by others?

Comments, including names and street addresses of respondents, will be available for public review at the street address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), along with Executive Order 13576, ''Delivering an Efficient, Effective, and Accountable Government,'' and the President's Memorandum for the Heads of Executive Departments and Agencies of January 21, 2009—Transparency and Open Government (74 FR 4685; January 26, 2009), which call on all Federal agencies to promote openness and transparency in Government by disclosing information to the public, we invite public comment on these permit applications before final action is taken. Under the MMPA, you may request a hearing on any MMPA application received. If you request a hearing, give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Service Director.

III. Permit Applications

A. Endangered Species

Applicant: Houston Zoo Inc., Houston, TX; PRT–45248B

The applicant requests a permit to export one female curassow (*Crax alberti*) from Houston Zoo, Houston, Texas to Nago Zoological and Botanical Gardens, Okinawa, Japan, for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Disney's Animal Kingdom, Bay Lake, FL; PRT–53174B

The applicant requests a permit to export feathers from captive-bred pink pigeons (*Nesoenas mayeri*) for the purpose of scientific research.

Applicant: The Wild Animal Park, Chittenango, NY; PRT–56456B

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for giant tortoises (*Chelonoidis nigra*), radiated tortoises (*Astrochelys radiata*), ring-tailed lemurs (*Lemur catta*), snow leopards (*Uncia uncia*), and leopards (*Panthera pardus*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: USFWS/Ecological Services Field Office, Cheyenne, WY; PRT–219999

The applicant requests renewal of their permit to export to and import from Toronto Zoo, Toronto, Ontario, Canada, captive hatched Wyoming toads (*Bufo hemiophrys baxteri*) for the purposes of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Edgar Hinkle, Lexington, NC; PRT–59964B

The applicant requests a permit to import a sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

B. Endangered Marine Mammals and Marine Mammals

Applicant: Tom Smith, Brigham Young University, Provo, UT; PRT–225854

The applicant requests a renewal of the permit to authorize harassment of polar bears (*Ursus maritimus*) by adjusting the video camera equipment, conducting aerial surveys, and conducting ground-truth surveys with snowmobiles near dens for the purpose of scientific research. This notification covers activities to be conducted by the applicant over the remainder of the 5-year period of the permit.

Concurrent with publishing this notice in the **Federal Register**, we are forwarding copies of the above applications to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2015–07218 Filed 3–27–15; 8:45 am]

BILLING CODE 4310–55–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–951]

Certain Lithium Metal Oxide Cathode Materials, Lithium-Ion Batteries for Power Tool Products Containing the Same, and Power Tools Products With Lithium-Ion Batteries Containing Same; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on February 20, 2015, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of BASF Corporation of Florham Park, New Jersey and UChicago Argonne LLC of Lemont, Illinois. A letter supplementing the complaint was filed on March 13, 2015. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain lithium metal oxide cathode materials, lithium metal-ion batteries for power tool products containing same, and power tool products with lithium-ion batteries containing same by reason of infringement of certain claims of U.S. Patent No. 6,677,082 (''the '082 patent'') and U.S. Patent No. 6,680,143 (''the '143 patent''). The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2014).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on March 23, 2015, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain lithium metal oxide cathode materials, lithium-ion batteries for power tool products containing same, and power tool products with lithium-ion batteries containing same by reason of infringement of one or more of claims 1–4, 7, 8, 13, and 14 of the '082 patent and claims 1–4, 8, 9, and 17 of the '143 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to Commission Rule 210.50(b)(1), 19 CFR 210.50(b)(1), the presiding administrative law judge shall take evidence or other information and hear arguments from the parties and other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue, which shall be limited to the statutory public interest factors set forth in 19 U.S.C. 1337(d)(1), (f)(1), (g)(1);

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

BASF Corporation, 100 Campus Drive, Florham Park, NJ 07932

UChicago Argonne LLC, 9700 S. Cass Avenue, Lemont, IL 60439

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Umicore N.V., Broekstraat 31, 1000 Brussels, Belgium

Umicore USA Inc., 3600 Glenwood Avenue, Suite 250, Raleigh, NC 27612

Makita Corporation, 3–11–8, Sumiyoschino, 446–0072 Anjo 446–0072 Aichi, Japan

Makita Corporation of America, 2650 Buford Highway, Buford, GA 30518

Makita U.S.A. Inc., 14930 Northam Street, La Mirada, CA 90638

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW., Suite 401, Washington, DC 20436; and

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: March 24, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–07146 Filed 3–27–15; 8:45 am]

BILLING CODE 7020–02–P

UNITED STATES INTERNATIONAL TRADE COMMISSION

[USITC SE–15–011]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: April 3, 2015 at 9:00 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: None.
2. Minutes.
3. Ratification List.
4. Vote in Inv. No. 731–TA–1269 (Preliminary) (Silicomanganese from Australia). The Commission is currently scheduled to complete and file its determination on April 6, 2015; views of

the Commission are currently scheduled to be completed and filed on April 13, 2015.

5. Outstanding action jackets: None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

Dated: Issued: March 25, 2015.

By order of the Commission.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2015–07282 Filed 3–26–15; 11:15 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging Proposed Consent Decree

In accordance with Departmental Policy, 28 CFR 50.7, notice is hereby given that a proposed Consent Decree in *Herberg, et al.* v. *United States Environmental Protection Agency, et al.,* Civil No. 14–1443 DWF/LIB, was lodged with the United States District Court for the District of Minnesota on February 27, 2015.

This proposed Consent Decree concerns a complaint filed against the United States by Thomas Lloyd Herberg, Bruce Allen Herberg, and D & G Drainage, Inc., pursuant to the Clean Water Act, 33 U.S.C. 1251, *et seq.,* and the Administrative Procedure Act, 5 U.S.C. 551, *et seq.,* to challenge an Administrative Order for Compliance issued to Plaintiffs for violating the Clean Water Act by discharging pollutants without a permit into waters of the United States. The proposed Consent Decree resolves these allegations, as well as the United States' potential enforcement counterclaims, by requiring the Plaintiffs to perform mitigation and to pay a civil penalty.

The Department of Justice will accept written comments relating to this proposed Consent Decree for thirty (30) days from the date of publication of this Notice. Please address comments to Daniel R. Dertke, Senior Attorney, United States Department of Justice, Environment and Natural Resources Division, Environmental Defense Section, Post Office Box 7611, Washington, DC 20044 and refer to *Herberg, et al.* v. *United States Environmental Protection Agency, et al.,* DJ #90–5–1–4–20160.

The proposed Consent Decree may be examined at the Clerk's Office, United States District Court for the District of Minnesota, United States Courthouse, 300 South Fourth Street, Suite 202, Minneapolis, MN 55415. In addition, the proposed Consent Decree may be examined electronically at *http://www.justice.gov/enrd/Consent_Decrees.html.*

Cherie L. Rogers,

Assistant Section Chief, Environmental Defense Section, Environment and Natural Resources Division.

[FR Doc. 2015–07150 Filed 3–27–15; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On March 24, 2015, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the District of Columbia in the lawsuit entitled *United States* v. *MTU America Inc.,* Civil Action No. 15–cv–429. The complaint was filed on the same day.

In the complaint, the United States, on behalf of the United States Environmental Protection Agency, seeks civil penalties and injunctive relief based on allegations that MTU America, Inc. (formerly Tognum America, Inc., and prior to that MTU Detroit Diesel), (hereinafter, ''MTU'') violated Sections 203(a) and 213 of Title II of the Clean Air Act (''CAA''), 42 U.S.C. 7522(a) and 7547, by selling 895 non-road engines without valid certificates of conformity. Under the Consent Decree, MTU will pay a civil penalty of $1.2 million, conduct three annual audits of its compliance with the CAA's Title II requirements, and remedy any noncompliance revealed by the audits.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *MTU America Inc.,* D.J. Ref. No. 90–5–2–1–10493. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $9.00 (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. 2015–07178 Filed 3–27–15; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Vehicle-Mounted Elevating and Rotating Work Platforms Standard

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Occupational Safety and Health Administration (OSHA) sponsored information collection request (ICR) titled, ''Vehicle-Mounted Elevating and Rotating Work Platforms Standard,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before April 29, 2015.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201501-1218-005* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OSHA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor—OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Vehicle-Mounted Elevating and Rotating Work Platforms Standard, commonly referred to as the Aerial Lifts Standard, information collection requirements codified in regulations 29 CFR 1910.67 that requires an Occupational Safety and Health Act of 1970 (OSHA Act) covered employer subject to the Standard to obtain a written certification of any field modification made to aerial lifts. Such a certification must be prepared in writing either by the manufacturer of the aerial lift or by a nationally recognized laboratory. This certification is to attest to the safety of the lift after modifications. OSH Act sections 2(b)(9), 6, and 8(c) authorize this information collection. *See* U.S.C. 651(b)(9), 655, and 657.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1218–0230.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on March 31, 2015. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on September 25, 2014 (79 FR 57583).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register.** In order to help ensure appropriate consideration, comments should mention OMB Control Number 1218–0230. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–OSHA.

Title of Collection: Vehicle-Mounted Elevating and Rotating Work Platforms Standard.

OMB Control Number: 1218–0230.

Affected Public: Private Sector—businesses or other for-profits.

Total Estimated Number of Respondents: 1,000.

Total Estimated Number of Responses: 1,000.

Total Estimated Annual Time Burden: 20 hours.

Total Estimated Annual Other Costs Burden: $0.

Dated: March 25, 2015.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2015–07207 Filed 3–27–15; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Trade Adjustment Assistance Community College and Career Training Grant Program Reporting Requirements

ACTION: Notice.

SUMMARY: On March 31, 2015, the Department of Labor (DOL) will submit the Employment and Training Administration (ETA) sponsored information collection request (ICR) titled, ''Trade Adjustment Assistance Community College and Career Training Grant Program Reporting Requirements,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before April 30, 2015.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201503-1205-019* (this link will only become active on April 1, 2015) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–ETA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor—OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue, NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064,

(these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for Trade Adjustment Assistance Community College and Career Training (TAACCCT) Grant Program Reporting Requirements, Form numbers ETA–9159 and ETA–9160, information collection that requires a grantee to submit quarterly progress reports with a narrative summary of a least two progress measures and at least two implementation measures identified by the grantee in the project work, plan. Every fourth quarter, the grantee submits an annual performance report with standardized outcome measures that will include aggregate data for program participants for the following ten outcome measures: Unique participants served/enrolled, total number of participants who have completed a grant-funded program of study, total number still retained in their programs of study, total number retained in other education programs, total number of credit hours completed, total number of earned credentials, total number pursuing further education after program of study completion, total number employed after program of study completion, total number retained in employment after program of study completion, and the total number of those employed at enrollment who receive a wage increase post-enrollment. These reports help the ETA gauge the effects of TAACCCT grants, identify grantees that could serve as useful models, and target technical assistance appropriately. Trade and Globalization Adjustment Assistance Act of 2009 section 1872 authorizes this information collection. *See* 19 U.S.C. 2371.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1205–0489. The current approval is scheduled to expire on March 31, 2015; however, the DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on December 30, 2014 (79 FR 78493).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section by April 30, 2015. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1205–0489. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–ETA.

Title of Collection: Trade Adjustment Assistance Community College and Career Training Grant Program Reporting Requirements.

OMB Control Number: 1205–0489.

Affected Public: Individuals or Households and State, Local, and Tribal, Governments.

Total Estimated Number of Respondents: 81,931.

Total Estimated Number of Responses: 848,032.

Total Estimated Annual Time Burden: 66,390 hours.

Total Estimated Annual Other Costs Burden: $0.

Dated: March 24, 2015.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2015–07132 Filed 3–27–15; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Acrylonitrile Standard

ACTION: Notice.

SUMMARY: On March 31, 2015, the Department of Labor (DOL) will submit the Occupational Safety and Health Administration (OSHA), sponsored information collection request (ICR) titled, ''Acrylonitrile Standard,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before April 30, 2015.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201501-1218-010* (this link will only become active on April 1, 2015) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OSHA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Acrylonitrile (AN) Standard information collection requirements codified in regulations 29 CFR 1910.1045. The Standard is an occupational safety and health standard that protects workers from the adverse health effects that may result from exposure to AN. The AN Standard information collection requirements are essential components that protect workers from occupational exposure. An Occupational Safety and Health Act of 1970 (OSH Act) covered employer subject to the Standard and employees use the information to implement the protection the Standard requires. The information collections contained in the AN Standard include notifying a worker of AN exposures; a written compliance program; a worker medical surveillance program; and the development, maintenance, and disclosure of workers' exposure monitoring and medical records. OSH Act sections 2(b)(9), 6, and 8(c) authorize this information collection. *See* 29 U.S.C. 651(b)(9), 655, and 657.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1218–0126.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on March 31, 2015. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on November 13, 2014 (79 FR 67463).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section by April 30, 2015. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1218–0126. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–OSHA.

Title of Collection: Acrylonitrile Standard.

OMB Control Number: 1218–0126.

Affected Public: Private Sector—business or other for-profits.

Total Estimated Number of Respondents: 16.

Total Estimated Number of Responses: 4,516.

Total Estimated Annual Time Burden: 1,999 hours.

Total Estimated Annual Other Costs Burden: $144,628.

Dated: March 25, 2015.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2015–07206 Filed 3–27–15; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Onsite Consultation Agreements

ACTION: Notice.

SUMMARY: On March 31, 2015, the Department of Labor (DOL) will submit the Occupational Safety and Health Administration (OSHA) sponsored information collection request (ICR) titled, ''Onsite Consultation Agreements,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before April 30, 2015.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201503-1218-003* (this link will only become active on April 1, 2015) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OSHA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Onsite Consultation Agreements information collection. The OSHA Onsite Consultation Service Program offers free and confidential advice to small and medium-sized businesses in all States across the country, with priority given to high-hazard worksites. The requirements specified in the Onsite Consultation regulations for cooperative agreements, 29 CFR part 1908, are necessary to ensure uniform delivery of onsite consultation services nationwide. The regulatory procedures specify the activities to be carried out by State Onsite Consultation Programs funded by the Federal government, as well as the responsibilities of employers

who receive onsite consultation services.

Information collection requirements set forth in the Onsite Consultation Program regulations are in two categories: State responsibilities and employer responsibilities. Eight regulatory provisions require State information collection activities. The Federal government provides ninety (90) percent of funds for onsite consultation services delivered by the States. Four requirements apply to employers and specify conditions for receiving the free onsite consultation services. Occupational Safety and Health Act of 1970 sections 7(c)(1) and 21(c) authorize this information collection. *See* 29 U.S.C. 656(c)(1) and 670.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1218–0110.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on March 31, 2015. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on January 26, 2015 (80 FR 3991).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section by April 30, 2015. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1218–0110. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–OSHA.

Title of Collection: Onsite Consultation Agreements.

OMB Control Number: 1218–0110.

Affected Public: State, Local, and Tribal Governments and Private Sector—businesses or other for-profits.

Total Estimated Number of Respondents: 24,052.

Total Estimated Number of Responses: 101,266.

Total Estimated Annual Time Burden: 215,704 hours.

Total Estimated Annual Other Costs Burden: $0.

Dated: March 24, 2015.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2015–07167 Filed 3–27–15; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Slings Standard

ACTION: Notice.

SUMMARY: On March 31, 2015, the Department of Labor (DOL) will submit the Occupational Safety and Health Administration (OSHA) sponsored information collection request (ICR) titled, ''Slings Standard,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before April 30, 2015.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201501–1218–002* (this link will only become active on April 1, 2015) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OSHA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor—OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Slings Standard information collection codified in regulations 29 CFR 1910.184. The Standard specifies several information collection requirements, depending on the type of sling. The purpose of each requirement is to prevent workers from using defective or deteriorated slings, thereby reducing the risk of death or serious injury caused by sling failure during material handling. Information on the identification tags, markings, and codings assists the employer in determining whether the sling can be used for the lifting task. Sling inspections enable early detection of faulty slings. Inspection and repair records provide the employer with information about when the last inspection was done and about the type of repairs made. This information provides some assurance about the condition of the slings. These records also provide the most efficient means for an OSHA compliance officer to determine whether an Occupational Safety and Health Act (OSH Act)

covered employer is complying with the Standard. Proof-testing certificates give employers, workers, and OSHA compliance officers assurance that the slings are safe to use. The certificates also provide the compliance officers with an efficient means to assess employer compliance with the Standard. OSH Act sections 2(b)(9), 6, and 8(c) authorize this information collection. *See* U.S.C. 651(b)(9), 655, and 657.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1218–0223.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on March 31, 2015. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on October 22, 2014 (79 FR 63172).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section by April 30, 2015. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1218–0223. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–OSHA.
Title of Collection: Slings Standard.
OMB Control Number: 1218–0223.
Affected Public: Private Sector—businesses or other for-profits.
Total Estimated Number of Respondents: 1,350,000.
Total Estimated Number of Responses: 303,076.
Total Estimated Annual Time Burden: 23,614 hours.
Total Estimated Annual Other Costs Burden: $0.

Dated: March 24, 2015.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2015–07166 Filed 3–27–15; 8:45 am]

BILLING CODE 4510–26–P

LIBRARY OF CONGRESS

Copyright Royalty Board

[Docket No. 15–0008–CRB–SATR (2015–19)]

Determination of Royalty Rates for Secondary Transmissions of Broadcasts by Satellite Carriers and Distributors

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Notice of Commencement of Proceeding and Solicitation of Petitions to Participate.

SUMMARY: The Copyright Royalty Judges (Judges) announce commencement of a proceeding to determine rates for the satellite carrier statutory license described in section 119 of the Copyright Act for the license period January 1, 2015, through December 31, 2019.

DATES: *Effective Date:* March 30, 2015.

Applicability Dates: These regulations apply to the license period January 1, 2015, to December 31, 2019.

ADDRESSES: This notice and request is also posted on the agency's Web site (*www.loc.gov/crb*) and on Regulations.gov (*www.regulations.gov*). Parties who plan to participate should see How to Submit Petitions to Participate in the Supplementary Information section below for physical addresses and further instructions.

FOR FURTHER INFORMATION CONTACT: Richard Strasser, Senior Attorney, or Kimberly Whittle, Attorney Advisor, by telephone at (202) 707–7658 or email at *crb@loc.gov.*

SUPPLEMENTARY INFORMATION: On December 4, 2014, Congress passed the STELA Reauthorization Act of 2014. Public Law 113–200. The provisions of the reauthorization act extend the satellite carrier statutory license provisions of the Copyright Act (Act) to December 31, 2019. *See* 17 U.S.C. 119(a). Pursuant to 17 U.S.C. 119(c)(1)(F), the Judges announce initiation of a proceeding to be conducted under chapter 8 of the Act. Entities wishing to participate in the rate-setting period must file a Petition to Participate and pay the $150 filing fee.

After receiving all Petitions to Participate, the Judges will give notice to all parties in interest and commence the Voluntary Negotiation Period, during which affected parties may agree on acceptable, applicable rates. If the parties agree, the Judges will give public notice of the agreed rates and consider comments in response to the notice. Once the rates are established, they may be subject to an annual cost-of-living adjustment under 17 U.S.C. 119(c)(2).[1]

Petitions To Participate

Parties filing petitions to participate must comply with the requirements of section 351.1(b) of the copyright royalty board's regulations. 37 CFR 351.1(b).

How To Submit Petitions To Participate:

Any party wishing to participate in the proceeding to determine satellite royalty rates for 2015 through 2019 shall submit to the Copyright Royalty Board the filing fee (US $150), an original Petition to Participate, five paper copies, and an electronic copy in Portable Document Format (PDF) that contains searchable, accessible text (not an image) on a CD or other portable memory device to only one of the following addresses.

U.S. mail: Copyright Royalty Board, P.O. Box 70977, Washington, DC 20024–0977; or

Overnight service (only USPS Express Mail is acceptable): Copyright Royalty Board, P.O. Box 70977, Washington, DC 20024–0977; or

Commercial courier: Address package to: Copyright Royalty Board, Library of

[1] The Judges did not give notice of a rate adjustment for 2015 because of the sunset provision relating to the statutory satellite retransmission license. *See* 17 U.S.C. 119 (c)(1)(E). With the STELA Reauthorization Act in place, the Judges now initiate this proceeding to determine rates for the period 2015 to 2019, inclusive.

Congress, James Madison Memorial Building, LM–403, 101 Independence Avenue SE., Washington, DC 20559–6000. Deliver to: Congressional Courier Acceptance Site, 2nd Street NE and D Street NE., Washington, DC; or

Hand delivery: Library of Congress, James Madison Memorial Building, LM–401, 101 Independence Avenue SE., Washington, DC 20559–6000.

Participants should conform filed electronic documents to the Judges' Guidelines for Electronic Documents, available online at *www.loc.gov/crb/docs/Guidelinesfor_Electronic_Documents.pdf*.

Dated: March 24, 2015.

Suzanne M. Barnett,

Chief Copyright Royalty Judges.

[FR Doc. 2015–07107 Filed 3–27–15; 8:45 am]

BILLING CODE 1410–72–P

NUCLEAR REGULATORY COMMISSION

Application for a License to Export High-Enriched Uranium

Pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) 110.70(b) ''Public Notice of Receipt of an Application,'' please take notice that the U.S. Nuclear Regulatory Commission (NRC) has received the following request for an export license. Copies of the request are available electronically through the Agencywide Documents Access and Management System and can be accessed through the Public Electronic Reading Room link *http://www.nrc.gov/reading-rm.html* at the NRC Homepage.

A request for a hearing or petition for leave to intervene may be filed within thirty days after publication of this notice in the **Federal Register** (FR). Any request for hearing or petition for leave to intervene shall be served by the requestor or petitioner upon the applicant, the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555; the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555; and the Executive Secretary, U.S. Department of State, Washington, DC 20520.

A request for a hearing or petition for leave to intervene may be filed with the NRC electronically in accordance with NRC's E-Filing rule promulgated in August 2007, 72 FR 49139; August 28, 2007. Information about filing electronically is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* To ensure timely electronic filing, at least five days prior to the filing deadline, the petitioner/requestor should contact the Office of the Secretary by email at *HEARINGDOCKET@NRC.GOV,* or by calling (301) 415–1677, to request a digital ID certificate and allow for the creation of an electronic docket.

In addition to a request for hearing or petition for leave to intervene, written comments, in accordance with 10 CFR 110.81, should be submitted within thirty days after publication of this notice in the **Federal Register** to Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Rulemaking and Adjudications.

The information concerning this application for an export license follows.

NRC EXPORT LICENSE APPLICATION

[Description of material]

Name of applicant, date of application, date received, application No., docket No.	Material type	Total quantity	End use	Destination
DOE/NNSA—Y–12 National Security Complex. February 25, 2015 ..... March 11, 2015 ..... XSNM3761 ..... 11006193	High-Enriched Uranium (93.35%).	7.56 kilograms uranium-235 contained in 8.1 kilograms uranium.	To fabricate and irradiate targets for the production of medical isotopes in the National Research Universal reactor at Canadian Nuclear Laboratories in Canada.	Canada

For the U.S. Nuclear Regulatory Commission.

Dated this 24th day of March 2015 at Rockville, Maryland.

David L. Skeen,

Deputy Director, Office of International Programs.

[FR Doc. 2015–07223 Filed 3–27–15; 8:45 am]

BILLING CODE 7590–01–P

PENSION BENEFIT GUARANTY CORPORATION

Submission of Information Collections for OMB Review; Comment Request; Reportable Events; Notice of Failure To Make Required Contributions

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of request for OMB approval of revised collections of information.

SUMMARY: The Pension Benefit Guaranty Corporation (PBGC) is requesting that the Office of Management and Budget (OMB) extend approval (with modifications), under the Paperwork Reduction Act, of two collections of information under PBGC's regulation on Reportable Events and Certain Other Notification Requirements (OMB control numbers 1212–0013 and 1212–0041, expiring March 31, 2015). This notice informs the public of PBGC's request and solicits public comment on the revised collections of information.

DATES: Comments must be submitted by April 29, 2015.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the Web site instructions for submitting comments.
- *Email: paperwork.comments@pbgc.gov.*
- *Fax:* 202–326–4224.

• *Mail or Hand Delivery:* Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005–4026.

Comments received, including personal information provided, will be posted to *www.pbgc.gov.*

Copies of the collections of information and comments may be obtained without charge by writing to Disclosure Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005–4026; visiting the Disclosure Division; faxing a request to 202–326–4042; or calling 202–326–4040 during normal business hours. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4040.) The reportable events regulation, forms, and instructions are available at *www.pbgc.gov.*

FOR FURTHER INFORMATION CONTACT: Daniel S. Liebman, Attorney (*Liebman.Daniel@PBGC.gov*), Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005–4026; 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: Section 4043 of the Employee Retirement Income Security Act of 1974 (ERISA) requires plan administrators and plan sponsors to report certain plan and employer events to PBGC. The reporting requirements give PBGC notice of events that indicate plan or employer financial problems. PBGC uses the information provided in determining what, if any, action it needs to take. For example, PBGC might need to institute proceedings to terminate a plan (placing it in trusteeship) under section 4042 of ERISA to ensure the continued payment of benefits to plan participants and their beneficiaries or to prevent unreasonable increases in PBGC's losses.

Section 303(k) of ERISA and section 430(k) of the Internal Revenue Code of 1986 (Code) impose a lien in favor of an underfunded single-employer plan that is covered by the termination insurance program under title IV of ERISA if (1) any person fails to make a contribution payment when due, and (2) the unpaid balance of that payment (including interest), when added to the aggregate unpaid balance of all preceding payments for which payment was not made when due (including interest), exceeds $1 million. (For this purpose, a plan is underfunded if its funding target attainment percentage is less than 100 percent.) The lien is upon all property and rights to property belonging to the person or persons that are liable for required contributions (*i.e.,* a contributing sponsor and each member of the controlled group of which that contributing sponsor is a member).

Only PBGC (or, at its direction, the plan's contributing sponsor or a member of the same controlled group) may perfect and enforce this lien. ERISA and the Code require persons committing payment failures to notify PBGC within 10 days of the due date whenever there is a failure to make a required payment and the total of the unpaid balances (including interest) exceeds $1 million.

The provisions of section 4043 of ERISA and of sections 303(k) of ERISA and 430(k) of the Code have been implemented in PBGC's regulation on Reportable Events and Certain Other Notification Requirements (29 CFR part 4043). Subparts B and C of the regulation deal with reportable events, and subpart D deals with failures to make required contributions.

PBGC has issued Forms 10 and 10-Advance (10–A) and related instructions under subparts B and C (approved under OMB control number 1212–0013) [1] and Form 200 and related instructions under subpart D (approved under OMB control number 1212–0041). OMB approval of both of these collections of information expires March 31, 2015. PBGC is requesting that OMB extend its approval for three years, with modifications. 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.

On April 3, 2013 (at 78 FR 20039), PBGC published a proposed rule that would revise its reportable events regulation. The 2013 proposal substituted a new system of waivers (safe harbors) to more effectively target troubled plans and reduce burden where possible without depriving PBGC of the information it needs to protect the pension insurance system. PBGC received 13 comment letters on the 2013 proposal. PBGC also held its first-ever regulatory public hearing, at which eight of the commenters discussed their comments. PBGC is developing a final rule, taking into account the comments and discussion at the public hearing. Because OMB approval of the current information collection will expire before the final rule is published, it is necessary for PBGC to request that OMB extend its approval.

[1] Forms 10 and 10–A are optional and may provide for reduced initial information submissions.

On January 23, 2015 (at 80 FR 3664), PBGC notified the public that it intended to submit revised forms and instructions to OMB for review. PBGC received no comments on the notice.

PBGC intends to revise the current forms and instructions to:

• Require that additional supporting and identifying information be provided (*e.g.,* separating filer's name from title, filer's email address, event date, notice due date, filing date, and why a filing is late, if applicable).

• Require more description of the pertinent facts relating to an event (*e.g.,* reason for a late contribution) and on information being included or missing with filing.

• Add an information requirement included in the regulation to Forms 10 and 10–A (for change in contributing sponsor or controlled group event).

• Provide enhanced instructions on the type of actuarial information required to be submitted.

• Include a note in the Form 10–A instructions stating that PBGC typically asks for additional information (which will be specified) to be submitted within seven days (or sooner, in some cases).

• Remove information requirements that PBGC no longer needs or can gather from public sources.

• Require additional information for certain events (*e.g.,* cumulative amounts missed for missed contribution events, actuarial information for liquidation events, additional loan documentation such as waivers and cross-defaults for loan default events).

• Require a signature and certification on Form 10 and Form 10–A as to the completeness and accuracy of the contents of the filing.

PBGC is also intending to make conforming, clarifying, formatting, and editorial changes.

PBGC estimates that it will receive 868 reportable event notices per year under subparts B and C of the reportable events regulation using Forms 10 and 10–A and that the average annual burden of this collection of information is 4,500 hours and approximately $214,470. PBGC estimates that it will receive 165 notices of failure to make required contributions per year under subpart D of the reportable events regulation using Form 200 and that the average annual burden of this collection of information is 990 hours and approximately $40,755.

PBGC is soliciting public comments to—

• evaluate whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including

whether the information will have practical utility;

• evaluate the accuracy of the agency's estimate of the burden of the proposed collections of information, including the validity of the methodologies and assumptions used;

• enhance the quality, utility, and clarity of the information to be collected; and

• minimize the burden of the collections 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.

Issued in Washington, DC, this 24th day of March, 2015.

Judith Starr,

General Counsel, Pension Benefit Guaranty Corporation.

[FR Doc. 2015–07271 Filed 3–27–15; 8:45 am]

BILLING CODE 7709–02–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–267, OMB Control No. 3235–0272]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension:

Rule 11a–2.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Rule 11a–2 (17 CFR 270.11a–2) under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) permits certain registered insurance company separate accounts, subject to certain conditions, to make exchange offers without prior approval by the Commission of the terms of those offers. Rule 11a–2 requires disclosure, in certain registration statements filed pursuant to the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) of any administrative fee or sales load imposed in connection with an exchange offer.

There are currently 652 registrants governed by Rule 11a–2. The Commission includes the estimated burden of complying with the information collection required by Rule 11a–2 in the total number of burden hours estimated for completing the relevant registration statements and reports the burden of Rule 11a–2 in the separate Paperwork Reduction Act (''PRA'') submissions for those registration statements (see the separate PRA submissions for Form N–3 (17 CFR 274.11b), Form N–4 (17 CFR 274.11c) and Form N–6 (17 CFR 274.11d). The Commission is requesting a burden of one hour for Rule 11a–2 for administrative purposes.

The estimate of average burden hours is made solely for the purposes of the PRA, and is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules or forms. With regard to Rule 11a–2, the Commission includes the estimate of burden hours in the total number of burden hours estimated for completing the relevant registration statements and reported on the separate PRA submissions for those statements (see the separate PRA submissions for Form N–3, Form N–4 and Form N–6).

The information collection requirements imposed by Rule 11a–2 are mandatory. Responses to the collection of information will not be kept confidential. 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 control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: March 24, 2015.

Brent J. Fields,

Secretary.

[FR Doc. 2015–07129 Filed 3–27–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74572; File No. SR–NYSEARCA–2015–22]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Extending the Pilot Period for the Exchange's Retail Liquidity Until September 30, 2015

March 24, 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 March 20, 2015, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (the ''Commission'') a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the pilot period for the Exchange's Retail Liquidity Program (the ''Retail Liquidity Program'' or the ''Program''), which is currently scheduled to expire on April 14, 2015, until September 30, 2015. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to extend the pilot period of the Retail Liquidity Program, currently scheduled to expire on April 14, 2015, until September 30, 2015.

Background

In December 2013, the Commission approved the Retail Liquidity Program on a pilot basis.[3] The Program is designed to attract retail order flow to the Exchange, and allows such order flow to receive potential price improvement. The Program is currently limited to trades occurring at prices equal to or greater than $1.00 per share. Under the Program, Retail Liquidity Providers (''RLPs'') are able to provide potential price improvement in the form of a non-displayed order that is priced better than the Exchange's best protected bid or offer (''PBBO''), called a Retail Price Improvement Order (''RPI''). When there is an RPI in a particular security, the Exchange disseminates an indicator, known as the Retail Liquidity Identifier, indicating that such interest exists. Retail Member Organizations (''RMOs'') can submit a Retail Order to the Exchange, which would interact, to the extent possible, with available contra-side RPIs.

The Retail Liquidity Program was approved by the Commission on a pilot basis. Pursuant to NYSE Arca Equities Rule 7.44(m), the pilot period for the Program is scheduled to end twelve months after the date of implementation. Because the Program was implemented on April 14, 2014, the pilot period for the Program ends on April 14, 2015.[4]

Proposal To Extend the Operation of the Program

The Exchange established the Retail Liquidity Program in an attempt to attract retail order flow to the Exchange by potentially providing price improvement to such order flow. The Exchange believes that the Program promotes competition for retail order flow by allowing Exchange members to submit RPIs to interact with Retail Orders. Such competition has the ability to promote efficiency by facilitating the price discovery process and generating additional investor interest in trading securities, thereby promoting capital formation. The Exchange believes that extending the pilot is appropriate because it will allow the Exchange and the Commission additional time to analyze data regarding the Program that the Exchange has committed to provide.[5] As such, the Exchange believes that it is appropriate to extend the current operation of the Program.[6] Through this filing, the Exchange seeks to amend NYSE Arca Equities Rule 7.44(m) and extend the current pilot period of the Program until September 30, 2015.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5),[8] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange believes that extending the pilot period for the Retail Liquidity Program is consistent with these principles because the Program is reasonably designed to attract retail order flow to the exchange environment, while helping to ensure that retail investors benefit from the better price that liquidity providers are willing to give their orders. Additionally, as previously stated, the competition promoted by the Program may facilitate the price discovery process and potentially generate additional investor interest in trading securities. The extension of the pilot period will allow the Commission and the Exchange to continue to monitor the Program for its potential effects on public price discovery, and on the broader market structure.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change simply extends an established pilot program for an additional six months, thus allowing the Retail Liquidity Program to enhance competition for retail order flow and contribute to the public price discovery process.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[9] and Rule 19b–4(f)(6) thereunder.[10] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[11] and Rule 19b–4(f)(6)(iii) thereunder.[12]

A proposed rule change filed under Rule 19b–4(f)(6)[13] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[14] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative before the pilot's expiration. The Exchange stated that an immediate operative date is necessary in order to immediately implement the proposed rule change so that member organizations could continue to benefit

[3] *See* Securities Exchange Act Release No. 71176 (December 23, 2013), 78 FR 79524 (December 30, 2013) (SR–NYSEArca–2013–107) (''RLP Approval Order'').

[4] The Exchange announced the implementation date by Trader Update, which is available here: *https://www.nyse.com/publicdocs/nyse/notifications/trader-update/2014_04_07_Arca_RLP%20GO%20LIVE.pdf.*

[5] *See* RLP Approval Order, *supra*, n. 3 at 79529.

[6] Concurrently with this filing, the Exchange has submitted a request for an extension of the exemption under Regulation NMS Rule 612 previously granted by the Commission that permits it to accept and rank the undisplayed RPIs. *See* Letter from Martha Redding, Asst. Corporate Secretary, NYSE Group, Inc. to Brent J. Fields, Secretary, Securities and Exchange Commission, dated March 19, 2015.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(6).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6)(iii).

from the pilot program without interruption after April 14, 2015. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because such waiver would allow the pilot to continue uninterrupted, thereby avoiding any potential investor confusion that could result from temporary interruption in the pilot program. For this reason, the Commission designates the proposal operative on April 14, 2015.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEARCA–2015–22 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2015–22. 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 offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2015–22, and should be submitted on or before April 20, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Brent J. Fields,

Secretary.

[FR Doc. 2015–07136 Filed 3–27–15; 8:45 am]

BILLING CODE 8011–01–P

[15] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[16] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74571; File No. SR–NYSEMKT–2015–19]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Rule 13—Equities Relating to Pegging Interest

March 24, 2015.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on March 17, 2015, NYSE MKT LLC (''Exchange'' or ''NYSE MKT'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 13—Equities (Orders and Modifiers) relating to pegging interest. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 13—Equities (''Rule 13'') relating to pegging interest to provide that if the protected best bid or offer (''PBBO'') is not within the range of the pegging interest, the pegging interest would peg to the ''next best-priced available *displayable* interest,'' rather than the ''next best-priced available interest.'' This amendment would therefore exclude non-displayed interest from consideration as part of the ''next best-priced available interest'' under the rule.

Background

Under current Rule 13, pegging interest pegs to prices based on (i) a PBBO, which may be available on the Exchange or an away market, or (ii) interest that establishes a price on the Exchange.[4] In addition, pegging interest will peg only within a price range specified by the floor broker submitting the order. Thus, if the PBBO is not within the specified price range of the pegging interest, the pegging interest will instead peg to the next available best-priced interest that is within the specified price range.[5] For example, if pegging interest to buy 100 shares has a specified price range up to $10.00, but the best protected bid (''PBB'') of 100 shares is $10.01, then such pegging interest could not peg to the $10.01 PBB because it is not within the specified price range of the pegging interest. The pegging interest would instead peg to

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* paragraph (a)(3) to Rule 13 governing pegging interest.

[5] *See* paragraph (a)(4) to Rule 13 governing pegging interest.

the next available best-priced interest within the specified price range of up to $10.00.[6]

The ''next available best-priced interest'' concept in the current rule was originally expressed in a different fashion (when pegging was based on the Exchange's BBO, rather than the PBBO), but the basic functionality has always been the same. Specifically, when the pegging interest was introduced in 2006 on the New York Stock Exchange LLC (''NYSE''), if the Exchange BBO was higher (lower) than the price limit on the pegging interest to buy (sell), the pegging interest would peg to the highest (lowest) price at which there was other interest within the pegging price range.[7] In 2008, the NYSE introduced Non-Displayed Reserve Orders, without changing the underlying functionality of pegging interest to exclude the prices of such orders from the evaluation of what constitutes the highest (lowest) price at which there is other interest available within the range of the pegging interest.[8] In 2011, the Exchange amended the rule governing pegging interest to make a non-substantive change to the rule text to use the term ''next available best-priced non-pegging interest'' to describe the highest (lowest) priced interest in the Exchange Book or a protected bid or offer on an away market to which pegging interest to buy (sell) could peg.[9] Accordingly, the next available best-priced interest for pegging interest to buy (sell) is the next highest (lowest)-priced buy (sell) interest within Exchange systems or an away market protected quote that is available for an execution at any given time. That interest could be same-side non-marketable displayable interest or same-side non-marketable non-displayable interest.

Taking the above example, assume that the next price points on the Exchange's book priced below the $10.01 PBB are a Non-Display Reserve Order to buy 100 for $9.99 and a Limit Order to buy 100 for $9.98. Because the Non-Display Reserve Order is the next available best-priced interest within the specified price range, the pegging interest would peg to the $9.99 price of the Non-Display Reserve Order.

Proposed Rule Change

The Exchange proposes to revise its rule to limit the type of interest to which pegging interest would peg if the PBBO is not within the specified price range of the pegging interest. As proposed, if the PBBO is not within the specified price range, the pegging interest would only peg to the next available best-priced *displayable* interest. The term ''displayable'' is defined in Rule 72(a)(i) as that portion of interest that could be published as, or as part of, the Exchange BBO and includes non-marketable odd-lot and round-lot orders.

Using the above example, under the proposed change, the pegging interest to buy would instead peg to the Limit Order to buy for $9.98, and not the higher-priced Non-Display Reserve Order to buy for $9.99.

The Exchange also proposes to make a conforming change to paragraph (c)(1) of Rule 13 to provide that if pegging interest would peg to a price that is locking or crossing the Exchange best bid or offer, the pegging interest would instead peg to the next available best-priced *displayable* interest that would not lock or cross the Exchange best bid or offer.

Currently, under any circumstance when pegging interest cannot peg to the PBBO, whether because of a price restriction or if the PBBO does not meet a minimum size designation, pegging interest pegs instead to the next available best-priced interest. For example, pursuant to paragraph (c)(5) of Rule 13 governing pegging interest, the Exchange offers an optional feature whereby pegging interest may be designated with a minimum size of same-side volume to which such pegging interest would peg. If the PBBO does not meet the optional minimum size designation, the pegging interest pegs to the next available best-priced interest, without regard to size.[10] Accordingly, the Exchange also proposes to make a related change to current paragraph (c)(5) (which is being renumbered as paragraph (b)(4)) to

- specify that, if the PBBO does not meet a minimum size requirement specified by the pegging interest, the pegging interest pegs to the next available best-priced interest, without regard to size, and
- modify current functionality so that only *displayable* interest may be pegged to in such circumstances.[11]

The Exchange also proposes non-substantive amendments to delete references to ''reserved'' paragraphs of the rule and renumber the rule accordingly.

Because of the technology changes associated with this proposed rule change, the Exchange will announce by Trader Update when this change will be

[6] *See* paragraph (a)(4)(A) to Rule 13 governing pegging interest. Similarly, if pegging interest would peg to a price that would lock or cross the Exchange best offer or bid, the pegging interest would instead peg to the next available best-priced interest that would not lock or cross the Exchange best bid or offer. *See* paragraph (c)(1) to Rule 13 governing pegging interest.

[7] On October 1, 2008, the Commission approved the Exchange's rule proposal to establish new membership, member firm conduct, and equity trading rules that were based on the existing NYSE rules to reflect that equities trading on the Exchange would be supported by the NYSE's trading system. *See* Securities Exchange Act Release No. 58705 (Oct. 1, 2008), 73 FR 58995 (Oct. 8, 2008) (SR–Amex–2008–63) (approval order). Because the Exchange's rules are based on the existing NYSE rules, the Exchange believes that pre-October 1, 2008 NYSE rule filings provide guidance concerning Exchange equity rules. *See* Securities Exchange Act Release No. 54577 (Oct. 5, 2006), 71 FR 60208, 60210–11 (Oct. 12, 2006) (SR–NYSE–2006–36) (''Pegging Approval Order'') (order approving, among other things, introduction of pegging functionality for Floor brokers, including ''if the Exchange best bid is higher than the ceiling price of a pegging buy-side e-Quote or d-Quote, the e-Quote or d-Quote would remain at its quote price *or the highest price at which there is other interest within its pegging price range,* whichever is higher (consistent with the limit price of the order underlying the e-Quote or d-Quote). Similarly, if the Exchange best offer is lower than the floor price of a pegging sell-side e-Quote or d-Quote, the e-Quote or d-Quote would remain at its quote price *or the lowest price at which there is other interest within its pegging price range,* whichever is lower (consistent with the limit price of the order underlying the e-Quote or d-Quote).'' (emphasis added)).

[8] *See* Securities Exchange Act Release No. 59022 (Nov. 26, 2008), 73 FR 73683 (Dec. 3, 2008) (SR–NYSEALTR–2008–10) (introducing Non-Display Reserve Orders).

[9] *See* Securities Exchange Act Release No. 66032 (Dec. 22, 2011), 76 FR 82009 (Dec. 29, 2011) (SR–NYSEAmex–2011–99) (''Because the next available best-priced non-pegging interest may be on an away market, the Exchange further proposes to amend paragraph (vii) to Supplementary Material .26 to specify that the non-pegging interest against which pegging interest pegs may either be available on the Exchange or may be a protected bid or offer on an away market.'') (''2011 Pegging Filing''); *see also* Securities Exchange Act Release No. 68305 (Nov. 28, 2012), 77 FR 71853, 71857 (Dec. 4, 2012) (SR–NYSEMKT–2012–67) (amending Exchange rule governing pegging to, among other things, consolidate rule text from separate parts of the then-existing rule in a streamlined format, including use of the term ''next available best-priced interest'') (''2012 Pegging Filing'').

[10] When the NYSE adopted this feature in 2006, it only considered the NYSE BBO for purposes of determining whether the size condition was met, and specifically excluded pegging interest that was pegging to the NYSE BBO. *See* Pegging Approval Order, *supra,* n. 7 at 60211. The Exchange now evaluates the minimum size requirement based on the PBBO instead of the Exchange BBO. *See* 2012 Pegging Filing, *supra,* n. 9 at 71858.

[11] The Exchange also proposes to delete the clause ''which may not be the PBB or PBO'' in current paragraph (c)(5), which is rule text that related to when primary pegging interest had an optional offset feature, in which case the minimum quantity would not have been evaluated against the PBBO because primary pegging interest with an offset would not have pegged to the PBBO. The Exchange did not implement the offset functionality and previously filed a rule change to delete the rule text relating to the optional offset. *See* Securities Exchange Act Release No. 71898 (April 8, 2014), 79 FR 20957 (April 14, 2014) (SR–NYSEMKT–2014–27) (amending rules governing pegging interest to conform to functionality that is available at the Exchange).

implemented, which will be within 30 days of the effective date of this filing.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Section 6(b)(5),[13] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Specifically, the proposed change is intended to respond to the concern raised by the Commission[14] that the current rule permitting pegging to prices of non-displayable same-side non-marketable interest could potentially allow the user of the pegging interest to ascertain the presence of hidden liquidity at those price levels. Eliminating that functionality to respond to the Commission concern (along with conforming changes in the relevant rule) is, therefore, consistent with the Act. Similarly, the Exchange believes that specifying in its rules how the Exchange treats pegging interest that cannot peg to the PBBO, whether because of a price or size restriction, would remove impediments to and perfect the mechanism of a free and open market because it would provide transparency regarding the Exchange's pegging functionality.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not intended to address any competitive issues but rather to specify and amend the functionality associated with pegging interest to respond to concerns raised regarding current functionality.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[15] and Rule 19b–4(f)(6) thereunder.[16] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[17]

A proposed rule change filed under Rule 19b–4(f)(6)[18] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[19] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange asserts that such a waiver is consistent with the protection of investors and the public interest because it would permit the Exchange to implement the proposed change as soon as the technology supporting the change is available, because it would respond to the Commission concerns that the current rule could potentially allow the user of pegging interest to ascertain the presence of hidden liquidity, and because it would provide transparency regarding the pegging functionality. The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[20]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.[21]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEMKT–2015–19 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2015–19. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] *See* Securities Exchange Act Release No. 74298 (Feb. 18, 2015), 80 FR 9770, 9772–73 (Feb. 24, 2015) (SR–NYSEMKT–2014–95) (Order instituting proceedings to determine whether to approve or disapprove a proposed rule change to Rule 13).

[15] 15 U.S.C. 78s(b)(3)(A)(iii).

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[18] 17 CFR 240.19b–4(f)(6).

[19] 17 CFR 240.19b–4(f)(6)(iii).

[20] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[21] 15 U.S.C. 78s(b)(3)(C).

filing will also be available for inspection and copying at the NYSE's principal office and on its Internet Web site at *www.nyse.com.* All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2015–19 and should be submitted on or before April 20, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Brent J. Fields,

Secretary.

[FR Doc. 2015–07135 Filed 3–27–15; 8:45 am]

BILLING CODE 8011–01–P

[22] 17 CFR 200.30–3(a)(59).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–526, OMB Control No. 3235–0584]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension:
Rule 12d1–1.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

An investment company (''fund'') is generally limited in the amount of securities the fund (''acquiring fund'') can acquire from another fund (''acquired fund''). Section 12(d) of the Investment Company Act of 1940 (the ''Investment Company Act'' or ''Act'')[1] provides that a registered fund (and companies it controls) cannot:

- Acquire more than three percent of another fund's securities;
- invest more than five percent of its own assets in another fund; or
- invest more than ten percent of its own assets in other funds in the aggregate.[2]

In addition, a registered open-end fund, its principal underwriter, and any registered broker or dealer cannot sell that fund's shares to another fund if, as a result:

- The acquiring fund (and any companies it controls) owns more than three percent of the acquired fund's stock; or
- all acquiring funds (and companies they control) in the aggregate own more than ten percent of the acquired fund's stock.[3]

Rule 12d1–1 under the Act provides an exemption from these limitations for ''cash sweep'' arrangements in which a fund invests all or a portion of its available cash in a money market fund rather than directly in short-term instruments.[4] An acquiring fund relying on the exemption may not pay a sales load, distribution fee, or service fee on acquired fund shares, or if it does, the acquiring fund's investment adviser must waive a sufficient amount of its advisory fee to offset the cost of the loads or distribution fees.[5] The acquired fund may be a fund in the same fund complex or in a different fund complex. In addition to providing an exemption from section 12(d)(1) of the Act, the rule provides exemptions from section 17(a) of the Act and rule 17d–1 thereunder, which restrict a fund's ability to enter into transactions and joint arrangements with affiliated persons.[6] These provisions would otherwise prohibit an acquiring fund from investing in a money market fund in the same fund complex,[7] and prohibit a fund that acquires five percent or more of the securities of a money market fund in another fund complex from making any additional investments in the money market fund.[8]

The rule also permits a registered fund to rely on the exemption to invest in an unregistered money market fund that limits its investments to those in which a registered money market fund may invest under rule 2a–7 under the Act, and undertakes to comply with all the other provisions of rule 2a–7.[9] In addition, the acquiring fund must reasonably believe that the unregistered money market fund (i) operates in compliance with rule 2a–7, (ii) complies with sections 17(a), (d), (e), 18, and 22(e) of the Act[10] as if it were a registered open-end fund, (iii) has adopted procedures designed to ensure that it complies with these statutory provisions, (iv) maintains the records required by rules 31a–1(b)(1), 31a–1(b)(2)(ii), 31a–1(b)(2)(iv), and 31a–1(b)(9);[11] and (v) preserves permanently, the first two years in an easily accessible place, all books and records required to be made under these rules.

Rule 2a–7 contains certain collection of information requirements. An unregistered money market fund that complies with rule 2a–7 would be subject to these collection of information requirements. In addition, the recordkeeping requirements under rule 31a–1 with which the acquiring fund reasonably believes the unregistered money market fund complies are collections of information for the unregistered money market fund. The adoption of procedures by unregistered money market funds to ensure that they comply with sections 17(a), (d), (e), 18, and 22(e) of the Act also constitute collections of information. By allowing funds to invest in registered and unregistered money market funds, rule 12d1–1 is intended to provide funds greater options for cash management. In order for a registered fund to rely on the exemption to invest in an unregistered money market fund, the unregistered money market fund must comply with certain collection of information requirements for registered money market funds. These requirements are intended to ensure that the unregistered money market fund has established procedures for collecting the information necessary to make adequate credit reviews of securities in its portfolio, as well as other recordkeeping

[1] *See* 15 U.S.C. 80a.

[2] *See* 15 U.S.C. 80a–12(d)(1)(A). If an acquiring fund is not registered, these limitations apply only with respect to the acquiring fund's acquisition of registered funds.

[3] *See* 15 U.S.C. 80a–12(d)(1)(B).

[4] *See* 17 CFR 270.12d1–1.

[5] *See* rule 12d1–1(b)(1).

[6] *See* 15 U.S.C. 80a–17(a), 15 U.S.C. 80a–17(d); 17 CFR 270.17d–1.

[7] An affiliated person of a fund includes any person directly or indirectly controlling, controlled by, or under common control with such other person. *See* 15 U.S.C. 80a–2(a)(3) (definition of ''affiliated person''). Most funds today are organized by an investment adviser that advises or provides administrative services to other funds in the same complex. Funds in a fund complex are generally under common control of an investment adviser or other person exercising a controlling influence over the management or policies of the funds. *See* 15 U.S.C. 80a–2(a)(9) (definition of ''control''). Not all advisers control funds they advise. The determination of whether a fund is under the control of its adviser, officers, or directors depends on all the relevant facts and circumstances. *See* Investment Company Mergers, Investment Company Act Release No. 25259 (Nov. 8, 2001) [66 FR 57602 (Nov. 15, 2001)], at n.11. To the extent that an acquiring fund in a fund complex is under common control with a money market fund in the same complex, the funds would rely on the rule's exemptions from section 17(a) and rule 17d–1.

[8] *See* 15 U.S.C. 80a–2(a)(3)(A), (B).

[9] *See* 17 CFR 270.2a–7.

[10] *See* 15 U.S.C. 80a–17(a), 15 U.S.C. 80a–17(d), 15 U.S.C. 80a–17(e), 15 U.S.C. 80a–18, 15 U.S.C. 80a–22(e).

[11] *See* 17 CFR 270.31a–1(b)(1), 17 CFR 270.31a–1(b)(2)(ii), 17 CFR 270.31a–1(b)(2)(iv), 17 CFR 270.31a–1(b)(9).

requirements that will assist the acquiring fund in overseeing the unregistered money market fund (and Commission staff in its examination of the unregistered money market fund's adviser).

The number of unregistered money market funds that would be affected by the proposal is an estimate based on the number of Commission exemptive applications that the Commission received in the past that sought relief for registered funds to purchase shares in an unregistered money market fund in excess of the section 12(d)(1) limits. The hour burden estimates for the condition that an unregistered money market fund comply with rule 2a–7 are based on the burden hours included in the Commission's 2009 and 2010 PRA submissions regarding rule 2a–7 (''rule 2a–7 submissions'').[12] The estimated average burden hours in this collection of information are made solely for purposes of the Paperwork Reduction Act and are not derived from a quantitative, comprehensive or even representative survey or study of the burdens associated with Commission rules and forms.

In the rule 2a–7 submissions, Commission staff made the following estimates with respect to aggregate annual hour and cost burdens for collections of information for each existing registered money market fund:

Documentation of credit risk analyses, and determinations regarding adjustable rate securities, asset backed securities, and securities subject to a demand feature or guarantee:
- 81 responses
- 410 hours of professional time
- Cost: $79,130.

Public Web site posting of monthly portfolio information:
- 12 responses
- 4.4 burden hours of professional time
- Cost: $12,584

The staff estimates that registered funds currently invest in 30 unregistered money market funds in excess of the statutory limits under rule 12d1–1.[13] Each of these unregistered money market funds engages in the collections of information described above. Accordingly, the staff estimates that unregistered money market funds complying with the collections of information described above engage in a total of 2790 annual responses under rule 12d1–1,[14] the aggregate annual burden hours associated with these responses is 12,432,[15] and the aggregate annual cost to funds is $2.75 million.[16]

In the rule 2a–7 submissions, Commission staff further estimated the aggregate annual hour and cost burdens for collections of information for fund complexes with registered money market funds as follows:

Review and revise procedures concerning stress testing:
- 1 response
- 7 burden hours of professional and director time
- Cost: $5,650

Draft, compile, and provide stress testing reports to board of directors:
- 10 responses
- 27 burden hours of director, professional, and support staff time
- Cost: $69,990

Maintain records of stress testing reports to board of directors:
- 10 responses
- 0.2 burden hours of support staff time
- Cost: $103

Maintain records of creditworthiness evaluations of repurchase counterparties:
- 1 response
- 2 burden hours of support staff time
- Cost: $124

Reporting of rule 17a–9 transactions:[17]
- 1 response
- 1 burden hour of legal time
- Cost: $305

In the rule 2a–7 submissions, Commission staff estimated that there are 163 fund complexes with 719 registered money market funds subject to rule 2a–7. The staff estimates that there are 30 fund complexes with unregistered money market funds invested in by mutual funds in excess of the statutory limits under rule 12d1–1.[18] Each of these fund complexes engages in the collections of information described above. Accordingly, the staff estimates that these fund complexes complying with the collections of information described above engage in a total of 690 annual responses under rule 12d1–1,[19] the aggregate annual burden hours associated with these responses is 1116,[20] and the aggregate annual cost to funds is $2,285,160.[21]

In the rule 2a–7 submissions, the staff further estimated the aggregate annual burdens for registered money market funds that amend their board procedures as follows:

Amendment of procedures designed to stabilize the fund's net asset value:
- 1 response
- 2.4 burden hours of director time
- Cost: $2,340

Consistent with the estimate in the rule 2a–7 submissions, Commission

[12] Securities and Exchange Commission, Request for OMB Approval of Extension for Approved Collection for Rule 2a–7 under the Investment Company Act of 1940 (OMB Control No. 3235–0268) (approved October 13, 2009); Securities and Exchange Commission, Request for OMB Approval of Revision for Approved Collection for Rule 2a–7 under the Investment Company Act of 1940 (OMB Control No. 3235–0268) (approved April 18, 2010).

[13] This estimate is based on the number of applications seeking exemptions to invest in unregistered money market funds filed with the Commission in 2005 (40), adjusted by the percentage change in registered money market funds from 2005 to November 2011 (870 to 641, according to the Investment Company Institute). This estimate may be understated because applicants generally did not identify the name or number of unregistered money market funds in which registered funds intended to invest, and each application also applies to unregistered money market funds to be organized in the future. Because the Commission adopted rule 12d1–1 in June 2006, 2005 is the last full year in which the Commission received applications seeking an exemption to invest in unregistered money market funds.

[14] The estimate is based on the following calculations: (30 funds × 81 responses for documentation of credit analyses and other determinations) = 2,340 responses. (30 funds × 12 responses for public Web site posting) = 360 responses. 2,340 responses + 360 responses = 2,790 responses.

[15] This estimate is based on the following calculations: (30 funds × 410 hours for documentation of credit analyses and other determinations) = 12,300 hours. (30 funds × 4.4 hours for public Web site posting) = 132 hours. 12,300 hours + 132 hours = 12,432 hours.

[16] This estimate is based on the following calculations: (30 funds × $79,130) = $2,373,900. (30 funds × $12,584) = $377,520. $2,373,900 + $377,520 = $2,751,420.

[17] *See* 17 CFR 270.17a–9.

[18] Given the fact that exemptive applications are generally filed on behalf of fund complexes rather than individual funds, the staff estimates that each of the exemptive applications upon which its estimates of the number of unregistered money market funds is based represents a separate fund complex. *See supra* note 13.

[19] The estimate is based on the following calculations: (30 fund complexes × 1 response for revision of procedures concerning stress testing) = 30 responses. (30 fund complexes × 10 responses to provide stress testing reports) = 300 responses. (30 fund complexes × 10 responses to maintain stress testing reports) = 300 responses. (30 fund complexes x 1 response to maintain records of creditworthiness) = 30 responses. (30 fund complexes × 1 response for reporting of rule 17a–9 transactions) = 30 responses. 30 responses + 300 responses + 300 responses + 30 responses + 30 responses = 690 responses.

[20] This estimate is based on the following calculations: (30 fund complexes × 7 hours for revision of procedures concerning stress testing) = 210 hours. (30 fund complexes × 27 hours to provide stress testing reports) = 810 hours. (30 fund complexes × 0.2 hours to maintain stress testing reports) = 6 hours. (30 fund complexes × 2 hours to maintain records of creditworthiness) = 60 hours. (30 fund complexes × 1 hour for reporting of rule 17a–9 transactions) = 30 hours. 210 hours + 810 hours + 6 hours + 60 hours + 30 hours = 1,116 hours.

[21] This estimate is based on the following calculations: (30 fund complexes × $5,650 for revision of procedures concerning stress testing) = $169,500. (30 fund complexes × $69,990 to provide stress testing reports) = $2,099,700. (30 fund complexes × $103 to maintain stress testing reports) = $3,090. (30 fund complexes × $124 to maintain records of creditworthiness) = $3,720. (30 fund complexes × $305 for reporting of rule 17a–9 transactions) = $9,150. $169,500 + $2,099,700 + $3,090 + $3,720 + $9,150 = $2,285,160.

staff estimates that approximately ¼, or 8, unregistered money market funds review and amend their board procedures each year. Accordingly, the staff estimates that unregistered money market funds complying with this collection of information requirement engage in a total of 8 annual responses under rule 12d1–1,[22] the aggregate annual burden hours associated with these responses is 19,[23] and the aggregate annual cost to funds to comply with this collection of information is $18,720.[24]

In the rule 2a–7 submissions, Commission staff further estimated the aggregate annual burdens for registered money market funds that experience an event of default or insolvency as follows:

Written record of board determinations and actions related to failure of a security to meet certain eligibility standards or an event of default of default or insolvency:
- 2 responses
- 1 burden hour of legal time
- Cost: $270

Notice to Commission of an event of default or insolvency:
- 1 response
- 1.5 burden hours of legal time
- Cost: $405

Consistent with the estimate in the rule 2a–7 submissions, Commission staff estimates that approximately 2 percent, or 1, unregistered money market fund experiences an event of default or insolvency each year. Accordingly, the staff estimates that one unregistered money market fund will comply with these collection of information requirements and engage in 3 annual responses under rule 12d1–1,[25] the aggregate annual burden hours associated with these responses is 2.5,[26] and the aggregate annual cost to funds is $675.[27]

In the rule 2a–7 submissions, Commission staff further estimated the aggregate annual burdens for newly registered money market funds as follows:

Establishment of written procedures designed to stabilize the fund's net asset value and guidelines for delegating board authority for determinations under the rule:
- 1 response
- 15.5 hours of director, legal, and support staff time
- Cost: $5,610.

Adopt procedures concerning stress testing:
- 1 response per fund complex
- 8.33 burden hours of professional and director time per fund complex
- Cost: $6,017 per fund complex

Commission staff estimates that the proportion of unregistered money market funds that intend to newly undertake the collection of information burdens of rule 2a–7 will be similar to the proportion of money market funds that are newly registered. Because of the recent decrease in registered money market funds and the lack of newly registered money market funds, the staff believes that there will be no unregistered money market funds that will undertake the collections of information required for newly registered money market funds.[28] As a result, the staff estimates that there will be no burdens associated with these collection of information requirements.

Accordingly, the estimated total number of annual responses under rule 12d1–1 for the collections of information described in the rule 2a–7 submissions is 3,491, the aggregate annual burden hours associated with these responses is 13,570, and the aggregate cost to funds is $5.1 million.[29]

Rules 31a–1(b)(1), 31a–1(b)(2)(ii), 31a–1(b)(2)(iv), and 31a–1(b)(9) require registered funds to keep certain records, which include journals and general and auxiliary ledgers, including ledgers for each portfolio security and each shareholder of record of the fund. Most of the records required to be maintained by the rule are the type that generally would be maintained as a matter of good business practice and to prepare the unregistered money market fund's financial statements. Accordingly, Commission staff estimates that the requirements under rules 31a–1(b)(1), 31a–1(b)(2)(ii), 31a–1(b)(2)(iv), and 31a–1(b)(9) would not impose any additional burden because the costs of maintaining these records would be incurred by unregistered money market funds in any case to keep books and records that are necessary to prepare financial statements for shareholders, to prepare the fund's annual income tax returns, and as a normal business custom.

Rule 12d1–1 also requires unregistered money market funds in which registered funds invest to adopt procedures designed to ensure that the unregistered money market funds comply with sections 17(a), (d), (e), and 22(e) of the Act. This is a one-time collection of information requirement that applies to unregistered money market funds that intend to comply with the requirements of rule 12d1–1. As discussed above, Commission staff estimates that because of the recent decrease in registered money market funds and the lack of newly registered money market funds there will be no unregistered money market funds that will undertake the collections of information required for newly registered money market funds.[30] For similar reasons, the Commission staff estimates that there will be no registered money market funds that will adopt procedures designed to ensure that the unregistered money market funds comply with sections 17(a), (d), (e), and 22(e) of the Act. The staff concludes that there will be no burdens associated with these collection of information requirements.

Commission staff further estimates that unregistered money market funds will incur costs to preserve records, as required under rule 2a–7. These costs will vary significantly for individual funds, depending on the amount of assets under fund management and whether the fund preserves its records in a storage facility in hard copy or has developed and maintains a computer system to create and preserve compliance records. In the rule 2a–7 submissions, Commission staff estimated that the amount an individual money market fund may spend ranges from $100 per year to $300,000. We have no reason to believe the range is different for unregistered money market funds. The Commission does not have specific information on the amount of assets managed by unregistered money market funds or the proportion of those assets held in small, medium-sized, or large unregistered money market funds. Accordingly, Commission staff estimates that unregistered money market funds in which registered funds invest in reliance on rule 12d1–1 are similar to registered money market funds in terms of amount and distribution of assets under

[22] The estimate is based on the following calculation: (8 funds × 1 response for board review and amendment of procedures) = 8 responses.

[23] This estimate is based on the following calculation: (8 funds × 2.4 hours for review and amendment of procedures) = 19.2 hours.

[24] This estimate is based on the following calculation: (8 funds × $2,340) = $18,720.

[25] The estimate is based on the following calculations: (1 fund × 2 responses) + (1 fund × 1 response) = 3 responses.

[26] This estimate is based on the following calculations: (1 fund × 1 hour) + (1 fund × 1.5 hours) = 2.5 hours.

[27] This estimate is based on the following calculations: (1 fund × $270) + (1 fund × $405) = $675.

[28] *See supra* note 13.

[29] These estimates are based upon the following calculations: 2790 + 690 + 8+ 3 = 3,491 annual responses; 12,432 + 1116 + 19 + 2.5 = 13,569.5 burden hours; and $2,751,420 + $2,285,160 + $18,720 + $675 = $5,055,975.

[30] *See supra* text accompanying note 28.

management.[31] Based on a cost of $0.0051295 per dollar of assets under management for small funds, $0.0005041 per dollar of assets under management for medium-sized funds and $0.0000009 per dollar of assets under management for large funds, the staff estimates compliance with rule 2–7 for these unregistered money market funds totals $3.9 million annually.[32]

Consistent with estimates made in the rule 2a–7 submissions, Commission staff estimates that unregistered money market funds also incur capital costs to create computer programs for maintaining and preserving compliance records for rule 2a–7 of $0.0000132 per dollar of assets under management. Based on the assets under management figures described above, staff estimates annual capital costs for all unregistered money market funds of $1.98 million.[33]

Commission staff further estimates that, even absent the requirements of rule 2a–7, money market funds would spend at least half of the amounts described above for record preservation ($2.0 million) and for capital costs ($0.99 million). Commission staff concludes that the aggregate annual costs of compliance with the rule are $2.0 million for record preservation and $0.99 million for capital costs.

The collections of information required for unregistered money market funds by rule 12d1–1 are necessary in order for acquiring funds to able to obtain the benefits described above. Notices to the Commission will not be kept confidential. 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 control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: March 24, 2015.

Brent J. Fields,

Secretary.

[FR Doc. 2015–07128 Filed 3–27–15; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74568; File No. SR–FINRA–2015–006]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Section 4(c) of Schedule A to the FINRA By-Laws To Increase Qualification Examination Fees

March 24, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 10, 2015, Financial Industry Regulatory Authority, Inc. (''FINRA'') 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 FINRA. FINRA has designated the proposed rule change as ''establishing or changing a due, fee or other charge'' under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend Section 4(c) of Schedule A to the FINRA By-Laws to increase qualification examination fees.

Below is the text of the proposed rule change. Proposed new language is in *italics;* proposed deletions are in brackets.

* * * * *

SCHEDULE A TO THE BY-LAWS OF THE CORPORATION

* * * * *

Section 4—Fees

(a) through (b) No Change.

(c) The following fees shall be assessed to each individual who registers to take an examination as described below. These fees are in addition to the registration fee described in paragraph (b) and any other fees that the owner of an examination that FINRA administers may assess.

Series 4	Registered Options Principal	[$100] *$105*
Series 6	Investment Company Products/Variable Contracts Representative	[$95] *$100*
Series 7	General Securities Representative	[$290] *$305*
Series 9	General Securities Sales Supervisor—Options Module	[$75] *$80*
Series 10	General Securities Sales Supervisor—General Module	[$120] *$125*
Series 11	Assistant Representative—Order Processing	[$75] *$80*
Series 14	Compliance Official	[$335] *$350*
Series 16	Supervisory Analyst	[$230] *$240*
Series 17	Limited Registered Representative	[$75] *$80*
Series 22	Direct Participation Programs Representative	[$95] *$100*
Series 23	General Securities Principal Sales Supervisor Module	[$95] *$100*
Series 24	General Securities Principal	[$115] *$120*
Series 26	Investment Company Products/Variable Contracts Principal	[$95] *$100*
Series 27	Financial and Operations Principal	[$115] *$120*

[31] In the rule 2a–7 submissions, the staff estimated that 757 registered money market funds have $3.8 trillion in assets under management, or $5 billion in assets under management per registered money market fund. The staff further estimated that 0.2% of those assets are held in small money market funds (funds with less than $50 million in assets under management), 3% are held in medium-sized money market funds (funds with $50 million to $1 billion in assets under management), and the remaining assets are held in large money market funds (funds with more than $1 billion in assets under management).

[32] This estimate is based on the following calculations: 30 unregistered money market funds × $5 billion = $150 billion. ($150 billion × 0.2% × $0.0051295) = $1.5 million for small funds. ($150 billion × 3% × 0.0005041) = $2.3 million for medium-sized funds. ($150 billion × 96.8% × 0.0000009) = $0.1 million for large funds. $1.5 million + $2.3 million + $0.1 million = $3.9 million. The estimate of cost per dollar of assets is the same as that used in the rule 2a–7 submissions. *See supra* note 12.

[33] This estimate is based on the following calculation: $150 billion × 0.0000132 = $1.98 million.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

Series 28	Introducing Broker-Dealer Financial and Operations Principal	[$95] *$100*
Series 37	Canada Module of S7 (Options Required)	[$175] *$185*
Series 38	Canada Module of S7 (No Options Required)	[$175] *$185*
Series 39	Direct Participation Programs Principal	[$90] *$95*
Series 42	Registered Options Representative	[$70] *$75*
Series 51	Municipal Fund Securities Limited Principal	[$95] *$105*
Series 52	Municipal Securities Representative	[$120] *$130*
Series 53	Municipal Securities Principal	[$105] *$115*
Series 55	Limited Representative—Equity Trader	[$105] *$110*
Series 62	Corporate Securities Limited Representative	[$90] *$95*
Series 72	Government Securities Representative	[$105] *$110*
Series 79	Investment Banking Qualification Examination	[$290] *$305*
Series 82	Limited Representative—Private Securities Offering	[$90] *$95*
Series 86	Research Analyst—Analysis	[$175] *$185*
Series 87	Research Analyst—Regulatory	[$125] *$130*
Series 99	Operations Professional	[$125] *$130*

(1) through (4) No Change.

(d) through (i) No Change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The proposed rule change amends Section 4(c) of Schedule A of the FINRA By-Laws to increase qualification examination fees. Persons engaged in the investment banking or securities business of a FINRA member who function as principals or representatives are required to register with FINRA in each category of registration appropriate to their functions.[5] Such individuals must pass an appropriate qualification examination before their registration can become effective. These mandatory qualification examinations cover a broad range of subjects regarding financial markets and products, individual responsibilities, securities industry rules, and regulatory structure. FINRA develops, maintains, and delivers all qualification examinations for individuals who are registered or seeking registration with FINRA. FINRA also administers and delivers examinations sponsored (*i.e.,* developed) by the Municipal Securities Rulemaking Board (''MSRB'') and other self-regulatory organizations, the North American Securities Administrators Association, the National Futures Association, and the Federal Deposit Insurance Corporation.

FINRA currently administers examinations electronically through the PROCTOR® system[6] at testing centers operated by vendors under contract with FINRA. FINRA charges an examination fee to candidates for FINRA-sponsored and co-sponsored examinations to cover the development, maintenance and delivery of these examinations. For qualification examinations sponsored by a FINRA client and administered by FINRA, FINRA charges a delivery fee that represents either a portion of or the entire examination fee for the examination.[7]

FINRA regularly conducts a comprehensive review of the examination fee structure, including an analysis of the costs associated with developing, administering, and delivering each examination, so that FINRA may better understand whether pricing changes are warranted and evaluate the financial condition of each qualification examination program. Based on the results of the review, FINRA may propose changes to better align the examination fee structure with the costs associated with the programs. When changes are warranted, fees are set at levels that are expected to meet cost and revenue objectives over a two-to-three year period to provide firms and examination candidates with a predictable cost environment.

In this regard, the most recent review revealed that certain operational costs have increased and, based on current information, will continue to increase over the next few years. In particular, these increased costs consist of: (1) Fees that vendors charge FINRA for delivering qualification examinations through their networks of test delivery centers; (2) staff labor associated with the development and maintenance of the qualification examinations; and (3) PROCTOR system maintenance and enhancement expenses.[8] FINRA believes that the proposed rule change will help to better align the examination program fees with these increased costs. Therefore, FINRA is proposing to amend Section 4(c) of Schedule A to the FINRA By-Laws to increase the fees for the qualification examinations set forth in Section 4(c).

FINRA has filed the proposed rule change for immediate effectiveness. FINRA is proposing that the implementation date of the proposed rule change will be April 1, 2015. Specifically, the proposed qualification examination fees would become effective for examination requests made in the CRD system on or after April 1, 2015.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(5) of the Act,[9] which requires, among other things, that FINRA rules provide for the equitable

[5] *See* NASD Rules 1021(a) and 1031(a), and NASD Rules 1022 and 1032. *See also* NASD Rules 1041 and 1050 and FINRA Rule 1230(b)(6) regarding the qualification and registration requirements for Order Processing Assistant Representatives, Research Analysts and Operations Professionals, respectively.

[6] PROCTOR is a computer system that is specifically designed for the administration and delivery of computer-based testing and training.

[7] The delivery fee represents a portion of the entire examination fee when a FINRA client has established an additional fee for an examination that it sponsors. For example, the fee to take the Series 51 (Municipal Fund Securities Limited Principal) examination is currently $155. Of this amount, $95 is the FINRA administration and delivery fee, and $60 is the development fee determined by the FINRA client, the MSRB. *See* MSRB Rule A–16.

[8] While delivery costs for examinations have increased over the last three years, delivery costs for qualification examinations are scheduled to stabilize in 2015 and 2016 based on FINRA's recently negotiated agreements with vendors that deliver the qualification examinations through their networks of test delivery centers.

[9] 15 U.S.C. 78*o*–3(b)(5).

allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system that FINRA operates or controls.

FINRA believes that the proposed rule change constitutes an equitable allocation of fees as the qualification examination fees will be assessed only on those individuals who take qualification examinations. In addition, all candidates who register for a particular qualification examination will be charged the same amount.

FINRA further believes that the proposed qualification examination changes are reasonable because they will more closely align the overall examination program fees with the overall costs associated with the programs. In this regard, FINRA notes that the last time that it increased fees for any of the qualification examinations set forth in Schedule A to the FINRA By-Laws was April 2012.[10] Since that time, FINRA's examination program expenses have increased and, based on current information, will continue to increase over the next few years. Specifically, FINRA has experienced cost increases relating to: (1) Fees that vendors charge FINRA for delivering qualification examinations through their networks of test delivery centers; (2) staff labor associated with the development and maintenance of the qualification examinations; and (3) PROCTOR system maintenance and enhancement expenses. [11]

To better align the fees and costs associated with the examination programs, FINRA is proposing modest fee increases. In this regard, FINRA notes that no qualification examination fee will increase by more than $15 and the majority of examination fees will increase by only $5. Accordingly, FINRA believes that the proposed qualification examination fee changes are equitably allocated and reasonable.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. FINRA believes that the proposed qualification examination fee changes have limited economic impacts on the industry.

Economic Impact Assessment

(a) Need for the Rule

FINRA seeks to set the qualification examination fees in such a manner as to meet expected program costs and revenues over a two-to-three year period in order to provide firms and examination candidates with a predicable cost environment. FINRA has determined that operational costs for the program have increased since FINRA last adjusted the fees in April 2012. FINRA also projects that these operational costs will continue to increase. As a result, FINRA has determined that a fee increase is needed to better align the examination program fees to meet these increased costs.

(b) Economic Baseline

The current examination fee structure and expected costs associated with the examination programs serve as an economic baseline for the proposed rule change. Qualification examination fees are charged directly to members that act as sponsors for individuals seeking to obtain qualifications through the examination programs. While some members may choose to absorb these costs directly, other members directly pass on the costs of taking qualification examinations to the sponsored individual. FINRA's qualification examination program expenses have increased over the past three years and are expected to continue to rise in the next few years. Specifically, the following expenses have increased and are expected to further increase in the next few years: (1) Fees that vendors charge FINRA for delivering qualification examinations through their networks of test delivery centers; (2) FINRA staff labor expenses associated with the development and maintenance of the qualification examinations; and (3) technology maintenance and enhancement expenses.[12]

In 2014, the total volume of qualification examinations was 130,830, sponsored by 2,813 member firms. The average volume per member firm was 47 qualification examinations. The median volume per member firm was four qualification examinations, as large member firms that employed more representatives contributed to the majority of the qualification examination enrollments. For example, the top 25 member firms with the highest qualification examination enrollments accounted for 52% of the total volume with an average of 2,704 enrollments per firm. In contrast, 70% of the overall member firms had less than 10 qualification examination enrollments. Equivalently in 2014, the number of persons enrolling for qualification examinations was 95,306, and the average number of enrollments per person was 1.4.

Historically, the fees collected by the qualification examination programs have provided a limited but stable contribution to FINRA's overall revenue. In the absence of the proposed rule change, the qualification examination programs would not be able to meet the target contribution margin, in addition to, covering increased costs in the coming years.

(c) Economic Impacts

Assuming stable qualification examination delivery volumes (defined by the number and type of qualification examinations provided), the contribution margin of the qualification examination programs is estimated to reach the target level in 2015 and 2016 if the proposed fee increases become effective in April 2015. Compared to 2014, the total increase in qualification examination fees is estimated to be $0.94 million in 2015 and $1.25 million in 2016. At the individual examination level, no qualification examination fee will increase by more than $15 and the majority of qualification examination fees will increase by $5.

The increases in the qualification examination fees would impose a burden on members or individuals that pay for these examinations. Compared to the current fee structure, the average increase in qualification examination fees per member firm is estimated to be $334 in 2015 and $446 in 2016. The median fee increase per member firm is estimated to be $34 in 2015 and $45 in 2016, as large member firms are expected to account for the majority of the examination enrollments. For example, the top 25 member firms with the highest enrollments are estimated to have an average increase of $18,459 in 2015 and $24,612 in 2016. For the member firms with less than 10 enrollments (which accounted for 70% of the overall member firms), the average increase per firm is estimated to be $26 in 2015 and $35 in 2016. In contrast with the dollar amount increases, assuming stable qualification examination delivery volumes, the percentage increases in qualification examination fees for member firms vary in a narrow range of 3% to 5% with an average of 4% in 2015 and 4% to 7% with an average of 5% in 2016. At the individual level, compared to 2014, the average qualification examination fee increase per person is estimated to be $10 in 2015 and $13 in 2016.

[10] *See* Securities Exchange Act Release No. 66465 (February 24, 2012), 77 FR 12635 (March 1, 2012) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2012–009).

[11] *See supra* note 8.

[12] *See supra* note 8.

FINRA does not believe that the proposed rule change would impact the competition among member firms, those who seek qualifications, or to the provision of member services. Based on the economic impact assessment, the proposed increases in qualification examination fees are limited. Moreover, they do not impose significantly different impacts on member firms with different sizes or business models. Furthermore, FINRA does not believe that the proposed rule change will create any competitive advantage for any individuals as all candidates who register for a particular qualification examination will be charged the same amount.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [13] and paragraph (f)(2) of Rule 19b–4 thereunder. [14] 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–FINRA–2015–006 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–FINRA–2015–006. 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 FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2015–006 and should be submitted on or before April 20, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. [15]

Brent J. Fields,

Secretary.

[FR Doc. 2015–07133 Filed 3–27–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74570; File No. SR–NYSE–2015–12]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Rule 13 Relating to Pegging Interest

March 24, 2015.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on March 17, 2015, New York Stock Exchange LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 13 (Orders and Modifiers) relating to pegging interest. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 13 relating to pegging interest to provide that if the protected best bid or offer (''PBBO'') is not within the range of the pegging interest, the pegging interest would peg to the ''next best-priced available *displayable* interest,'' rather than the ''next best-priced available interest.'' This amendment would therefore exclude non-displayed interest from consideration as part of the ''next best-priced available interest'' under the rule.

Background

Under current Rule 13, pegging interest pegs to prices based on (i) a PBBO, which may be available on the Exchange or an away market, or (ii)

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[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(2).

[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

interest that establishes a price on the Exchange.[4] In addition, pegging interest will peg only within a price range specified by the floor broker submitting the order. Thus, if the PBBO is not within the specified price range of the pegging interest, the pegging interest will instead peg to the next available best-priced interest that is within the specified price range.[5] For example, if pegging interest to buy 100 shares has a specified price range up to $10.00, but the best protected bid (''PBB'') of 100 shares is $10.01, then such pegging interest could not peg to the $10.01 PBB because it is not within the specified price range of the pegging interest. The pegging interest would instead peg to the next available best-priced interest within the specified price range of up to $10.00.[6]

The ''next available best-priced interest'' concept in the current rule was originally expressed in a different fashion (when pegging was based on the Exchange's BBO, rather than the PBBO), but the basic functionality has always been the same. Specifically, when the pegging interest was introduced in 2006, if the Exchange BBO was higher (lower) than the price limit on the pegging interest to buy (sell), the pegging interest would peg to the highest (lowest) price at which there was other interest within the pegging price range.[7] In 2008, the Exchange introduced Non-Displayed Reserve Orders, without changing the underlying functionality of pegging interest to exclude the prices of such orders from the evaluation of what constitutes the highest (lowest) price at which there is other interest available within the range of the pegging interest.[8] In 2011, the Exchange amended the rule governing pegging interest to make a non-substantive change to the rule text to use the term ''next available best-priced non-pegging interest'' to describe the highest (lowest) priced interest in the Exchange Book or a protected bid or offer on an away market to which pegging interest to buy (sell) could peg.[9] Accordingly, the next available best-priced interest for pegging interest to buy (sell) is the next highest (lowest)-priced buy (sell) interest within Exchange systems or an away market protected quote that is available for an execution at any given time. That interest could be same-side non-marketable displayable interest or same-side non-marketable non-displayable interest.

Taking the above example, assume that the next price points on the Exchange's book priced below the $10.01 PBB are a Non-Display Reserve Order to buy 100 for $9.99 and a Limit Order to buy 100 for $9.98. Because the Non-Display Reserve Order is the next available best-priced interest within the specified price range, the pegging interest would peg to the $9.99 price of the Non-Display Reserve Order.

Proposed Rule Change

The Exchange proposes to revise its rule to limit the type of interest to which pegging interest would peg if the PBBO is not within the specified price range of the pegging interest. As proposed, if the PBBO is not within the specified price range, the pegging interest would only peg to the next available best-priced *displayable* interest. The term ''displayable'' is defined in Rule 72(a)(i) as that portion of interest that could be published as, or as part of, the Exchange BBO and includes non-marketable odd-lot and round-lot orders.

Using the above example, under the proposed change, the pegging interest to buy would instead peg to the Limit Order to buy for $9.98, and not the higher-priced Non-Display Reserve Order to buy for $9.99.

The Exchange also proposes to make a conforming change to paragraph (c)(1) of Rule 13 to provide that if pegging interest would peg to a price that is locking or crossing the Exchange best bid or offer, the pegging interest would instead peg to the next available best-priced *displayable* interest that would not lock or cross the Exchange best bid or offer.

Currently, under any circumstance when pegging interest cannot peg to the PBBO, whether because of a price restriction or if the PBBO does not meet a minimum size designation, pegging interest pegs instead to the next available best-priced interest. For example, pursuant to paragraph (c)(5) of Rule 13 governing pegging interest, the Exchange offers an optional feature whereby pegging interest may be designated with a minimum size of same-side volume to which such pegging interest would peg. If the PBBO does not meet the optional minimum size designation, the pegging interest pegs to the next available best-priced interest, without regard to size.[10] Accordingly, the Exchange also proposes to make a related change to current paragraph (c)(5) (which is being renumbered as paragraph (b)(4)) to

- specify that, if the PBBO does not meet a minimum size requirement specified by the pegging interest, the pegging interest pegs to the next available best-priced interest, without regard to size, and
- modify current functionality so that only *displayable* interest may be pegged [sic] in such circumstances.[11]

[4] *See* paragraph (a)(3) to Rule 13 governing pegging interest.

[5] *See* paragraph (a)(4) to Rule 13 governing pegging interest.

[6] *See* paragraph (a)(4)(A) to Rule 13 governing pegging interest. Similarly, if pegging interest would peg to a price that would lock or cross the Exchange best offer or bid, the pegging interest would instead peg to the next available best-priced interest that would not lock or cross the Exchange best bid or offer. *See* paragraph (c)(1) to Rule 13 governing pegging interest.

[7] *See* Securities Exchange Act Release No. 54577 (Oct. 5, 2006), 71 FR 60208, 60210–11 (Oct. 12, 2006) (SR–NYSE–2006–36) (''Pegging Approval Order'') (order approving, among other things, introduction of pegging functionality for Floor brokers, including ''if the Exchange best bid is higher than the ceiling price of a pegging buy-side e-Quote or d-Quote, the e-Quote or d-Quote would remain at its quote price *or the highest price at which there is other interest within its pegging price range,* whichever is higher (consistent with the limit price of the order underlying the e-Quote or d-Quote). Similarly, if the Exchange best offer is lower than the floor price of a pegging sell-side e-Quote or d-Quote, the e-Quote or d-Quote would remain at its quote price *or the lowest price at which there is other interest within its pegging price range,* whichever is lower (consistent with the limit price of the order underlying the e-Quote or d-Quote).'' (emphasis added)).

[8] *See* Securities Exchange Act Release No. 58845 (Oct. 24, 2008), 73 FR 64379 (Oct. 29, 2008) (SR–NYSE–2008–46) (introducing Non-Display Reserve Orders).

[9] *See* Securities Exchange Act Release No. 66031 (Dec. 22, 2011), 76 FR 82024 (Dec. 29, 2011) (SR–NYSE–2011–62) (''Because the next available best-priced non-pegging interest may be on an away market, the Exchange further proposes to amend paragraph (vii) to Supplementary Material .26 to specify that the non-pegging interest against which pegging interest pegs may either be available on the Exchange or may be a protected bid or offer on an away market.'') (''2011 Pegging Filing''); *see also* Securities Exchange Act Release No. 68302 (Nov. 27, 2012), 77 FR 71658, 71662 (Dec. 3, 2012) (SR–NYSE–2012–65) (amending Exchange rule governing pegging to, among other things, consolidate rule text from separate parts of the then-existing rule in a streamlined format, including use of the term ''next available best-priced interest'') (''2012 Pegging Filing'').

[10] When the Exchange adopted this feature in 2006, the Exchange only considered the Exchange BBO for purposes of determining whether the size condition was met, and specifically excluded pegging interest that was pegging to the Exchange BBO. *See* Pegging Approval Order, *supra,* n. 7 at 60211. The Exchange now evaluates the minimum size requirement based on the PBBO instead of the Exchange BBO. *See* 2012 Pegging Filing, *supra,* n. 9 at 71663.

[11] The Exchange also proposes to delete the clause ''which may not be the PBB or PBO'' in current paragraph (c)(5), which is rule text that related to when primary pegging interest had an optional offset feature, in which case the minimum quantity would not have been evaluated against the PBBO because primary pegging interest with an offset would not have pegged to the PBBO. The Exchange did not implement the offset functionality and previously filed a rule change to delete the rule text relating to the optional offset. *See* Securities Exchange Act Release No. 71897 (April 8, 2014), 79 FR 20953 (April 14, 2014) (SR–NYSE–2014–16) (amending rules governing pegging interest to

Continued

The Exchange also proposes non-substantive amendments to delete references to ''reserved'' paragraphs of the rule and renumber the rule accordingly.

Because of the technology changes associated with this proposed rule change, the Exchange will announce by Trader Update when this change will be implemented, which will be within 30 days of the effective date of this filing.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Section 6(b)(5),[13] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Specifically, the proposed change is intended to respond to the concern raised by the Commission[14] that the current rule permitting pegging to prices of non-displayable same-side non-marketable interest could potentially allow the user of the pegging interest to ascertain the presence of hidden liquidity at those price levels. Eliminating that functionality to respond to the Commission concern (along with conforming changes in the relevant rule) is, therefore, consistent with the Act. Similarly, the Exchange believes that specifying in its rules how the Exchange treats pegging interest that cannot peg to the PBBO, whether because of a price or size restriction, would remove impediments to and perfect the mechanism of a free and open market because it would provide transparency regarding the Exchange's pegging functionality.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not intended to address any competitive issues but rather to specify and amend the functionality associated with pegging interest to respond to concerns raised regarding current functionality.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[15] and Rule 19b–4(f)(6) thereunder.[16] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[17]

A proposed rule change filed under Rule 19b–4(f)(6)[18] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[19] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange asserts that such a waiver is consistent with the protection of investors and the public interest because it would permit the Exchange to implement the proposed change as soon as the technology supporting the change is available, because it would respond to the Commission concerns that the current rule could potentially allow the user of pegging interest to ascertain the presence of hidden liquidity, and because it would provide transparency regarding the pegging functionality. The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[20]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.[21]

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–NYSE–2015–12 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2015–12. 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

conform to functionality that is available at the Exchange).

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] *See* Securities Exchange Act Release No. 74298 (Feb. 18, 2015), 80 FR 9770, 9772–73 (Feb. 24, 2015) (SR–NYSEMKT–2014–95) (Order instituting proceedings to determine whether to approve or disapprove a proposed rule change to NYSE MKT, LLC Rule 13—Equities, which is based on NYSE Rule 13).

[15] 15 U.S.C. 78s(b)(3)(A)(iii).

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[18] 17 CFR 240.19b–4(f)(6).

[19] 17 CFR 240.19b–4(f)(6)(iii).

[20] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[21] 15 U.S.C. 78s(b)(3)(C).

public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the NYSE's principal office and on its Internet Web site at *www.nyse.com.* All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2015–12 and should be submitted on or before April 20, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Brent J. Fields,

Secretary.

[FR Doc. 2015–07134 Filed 3–27–15; 8:45 am]

BILLING CODE 8011–01–P

[22] 17 CFR 200.30–3(a)(59).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–216, OMB Control No. 3235–0243]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension:
Rule 206(3)–2.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Rule 206(3)–2, (17 CFR 275.206(3)–2) which is entitled ''Agency Cross Transactions for Advisory Clients,'' permits investment advisers to comply with section 206(3) of the Investment Advisers Act of 1940 (the ''Act'') (15 U.S.C. 80b–6(3)) by obtaining a client's blanket consent to enter into agency cross transactions (*i.e.,* a transaction in which an adviser acts as a broker to both the advisory client and the opposite party to the transaction). Rule 206(3)–2 applies to all registered investment advisers. In relying on the rule, investment advisers must provide certain disclosures to their clients. Advisory clients can use the disclosures to monitor agency cross transactions that affect their advisory account. The Commission also uses the information required by Rule 206(3)–2 in connection with its investment adviser inspection program to ensure that advisers are in compliance with the rule. Without the information collected under the rule, advisory clients would not have information necessary for monitoring their adviser's handling of their accounts and the Commission would be less efficient and effective in its inspection program.

The information requirements of the rule consist of the following: (1) Prior to obtaining the client's consent, appropriate disclosure must be made to the client as to the practice of, and the conflicts of interest involved in, agency cross transactions; (2) at or before the completion of any such transaction, the client must be furnished with a written confirmation containing specified information and offering to furnish upon request certain additional information; and (3) at least annually, the client must be furnished with a written statement or summary as to the total number of transactions during the period covered by the consent and the total amount of commissions received by the adviser or its affiliated broker-dealer attributable to such transactions.

The Commission estimates that approximately 464 respondents use the rule annually, necessitating about 32 responses per respondent each year, for a total of 14,848 responses. Each response requires an estimated 0.5 hours, for a total of 7,424 hours. The estimated average burden hours are made solely for the purposes of the Paperwork Reduction Act and are not derived from a comprehensive or representative survey or study of the cost of Commission rules and forms.

This collection of information is found at (17 CFR 275.206(3)–2) and is necessary in order for the investment adviser to obtain the benefits of Rule 206(3)–2. The collection of information requirements under the rule is mandatory. Information subject to the disclosure requirements of Rule 206(3)–2 does not require submission to the Commission; and, accordingly, the disclosure pursuant to the rule is not kept confidential.

Commission-registered investment advisers are required to maintain and preserve certain information required under Rule 206(3)–2 for five (5) years. The long-term retention of these records is necessary for the Commission's inspection program to ascertain compliance with the Advisers Act.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: March 24, 2015.

Brent J. Fields,

Secretary.

[FR Doc. 2015–07127 Filed 3–27–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension:
Rule 6c–7; SEC File No. 270–269, OMB Control No. 3235–0276.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Rule 6c–7 (17 CFR 270.6c–7) under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) (''1940 Act'') provides exemption from certain provisions of Sections 22(e) and 27 of the 1940 Act for registered separate accounts offering variable annuity contracts to certain employees of Texas institutions of higher education participating in the Texas Optional Retirement Program. There are

approximately 50 registrants governed by Rule 6c–7. The burden of compliance with Rule 6c–7, in connection with the registrants obtaining from a purchaser, prior to or at the time of purchase, a signed document acknowledging the restrictions on redeem ability imposed by Texas law, is estimated to be approximately 3 minutes per response for each of approximately 2,300 purchasers annually (at an estimated $64 per hour),[1] for a total annual burden of 115 hours (at a total annual cost of $7,360).

Rule 6c–7 requires that the separate account's registration statement under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) include a representation that Rule 6c–7 is being relied upon and is being complied with. This requirement enhances the Commission's ability to monitor utilization of and compliance with the rule. There are no recordkeeping requirements with respect to Rule 6c–7.

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act, and is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules or forms. The Commission does not include in the estimate of average burden hours the time preparing registration statements and sales literature disclosure regarding the restrictions on redeem ability imposed by Texas law. The estimate of burden hours for completing the relevant registration statements are reported on the separate PRA submissions for those statements. (See the separate PRA submissions for Form N–3 (17 CFR 274.11b) and Form N–4 (17 CFR 274.11c).)

Complying with the collection of information requirements of the rules is necessary to obtain a benefit. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: March 24, 2015.

Brent J. Fields,

Secretary.

[FR Doc. 2015–07130 Filed 3–27–15; 8:45 am]

BILLING CODE 8011–01–P

[1] $64/hour figure for a Compliance Clerk is from SIFMA's Office Salaries in the Securities Industry 2013 survey, modified by Commission staff to account for an 1800-hour work year and multiplied by 2.93 to account for bonuses, firm size, employee benefits and overhead.

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2013–0058]

Model Specifications for Breath Alcohol Ignition Interlock Devices (BAIIDs)

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Technical corrections; proposed changes and request for comments.

SUMMARY: NHTSA published a notice in the **Federal Register** on May 8, 2013, (78 FR 26849; NHTSA Docket 2013–0058) that revised the Model Specifications for Breath Alcohol Ignition Interlock Devices (BAIIDs). The text of the notice contained some typographical and technical errors. This document describes and corrects those errors. This notice also proposes some additional changes to the BAIID Model Specifications and requests comments on the proposed changes.

DATES: The technical corrections contained in this notice are effective on March 30, 2015. Regarding the proposed changes contained in this notice, written comments may be submitted to this agency and must be received no later than April 29, 2015.

ADDRESSES: You may submit comments identified by DOT Docket ID Number NHTSA–2013–0058 by any of the following methods:

- *Electronic submissions:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* 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.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Eastern Time, Monday through Friday, except Federal holidays. Regardless of how you submit your comments, you should identify the Docket number of this document.

Instructions: For detailed instructions on submitting comments and additional information, see *http://www.regulations.gov.* Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the ''Privacy Act'' heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the complete User Notice and Privacy Notice for Reglations.gov at *http://www.regulations.gov/search/footer/privacyanduse.jsp.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* at any time or visit the West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Eastern Time, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

For technical issues: Ms. De Carlo Ciccel, Behavioral Research Division, NTI–131, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; Telephone number: (202) 366–1694; Email: *decarlo.ciccel@dot.gov.*

For legal issues: Ms. Jin Kim, Attorney-Advisor, Office of the Chief Counsel, NCC–113, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; Telephone number: (202) 366–1834; Email: *jin.kim@dot.gov.*

SUPPLEMENTARY INFORMATION: NHTSA published a notice in the **Federal Register** on May 8, 2013, (78 FR 26849; NHTSA Docket 2013–0058) that revised the Model Specifications for Breath Alcohol Ignition Interlock Devices (BAIIDs).

The notice that was published on May 8, 2013, went into effect one year later, on May 8, 2014. As explained in the 2013 notice, NHTSA considered whether it should evaluate ignition interlocks against the Model Specifications and publish a conforming products list (CPL) of devices that meet the specifications. For reasons described in some detail in the 2013 notice, NHTSA explained that it would delay

rendering a decision about the feasibility and timing of a CPL until more information is available. NHTSA stated, in the notice, that it planned to conduct an assessment to determine whether establishing and maintaining a CPL is feasible, prior to making a decision.

Following publication of the 2013 notice, NHTSA initiated such an assessment. During the course of the assessment, NHTSA identified some aspects of the Model Specifications that may warrant clarification and/or modification. In addition, the agency received written communications from a number of organizations, including interlock providers, a testing laboratory, the Association of Ignition Interlock Program Administrators (AIIPA) and others, which brought some typographical and technical errors to the agency's attention and/or sought clarification regarding some elements of the Model Specifications. These written communications and our responses have been placed in our public docket (NHTSA–2013–0058).

This notice describes and corrects the technical errors. These technical corrections will take effect immediately. This notice also proposes some revisions to the Model Specifications and requests comments on the proposed changes.

A. Technical Corrections (Which Will Take Effect Immediately)

The following changes are considered by the agency to be technical corrections. They will take effect immediately upon publication of this notice in the **Federal Register**.

Test 9. Tampering and Circumvention—e. Cooled 0.032 BrAC Sample

In the **Federal Register** notice published on May 8, 2013, Test 9e in the Model Specifications indicated that a .032 sample should be ''cooled to ice temperature''.

This notice inserts the word ''water'' and the parenthetical ''(0°C/32°F)'' to clarify that the sample should be ''cooled to ice water temperature,'' which is 0°C (32°F).

Test 11. Altitude

In the **Federal Register** notice published on May 8, 2013, Test 11 in the Model Specifications was entitled ''High Altitude'' (78 FR 26865). However, it covers tests for both high altitude (low pressure) and low altitude (high pressure) conditions.

This notice corrects the title for the test to read, ''Altitude.'' The tests themselves have not been changed.

Test 16. Data Integrity and Format

In the **Federal Register** notice published on May 8, 2013, there was a reference under Test 16 to Appendix D (78 FR 26866). This was a typographical error. There were only two appendices to that notice, Appendix A and Appendix B.

This notice corrects that reference to Appendix B.

B. Proposed Changes (About Which We Request Comments)

The following changes are being proposed by the agency. The agency requests comments on these proposed changes.

Test 8. Retest

Test 8 of the Model Specifications include a series of tests to simulate the BAIID functions that must operate in connection with retests once the vehicle has been started, including an indication to the driver that a retest must be taken. Two commenters requested clarification regarding this test. Specifically, their questions related to provisions requiring that the BAIID ''indicate the need for a service call'' and stating that ''the BAIID must not allow the vehicle to start without a service call.''

As provided in Test 8 of the Model Specifications, a failed retest must trigger an alert to the driver and be flagged (recorded) on the interlock data logger. A missed retest also must be flagged (recorded) on the data logger. Conformance will require verification that alerts were made and that these events were recorded on the data logger.

In the **Federal Register** notice published on May 8, 2013, NHTSA expressed agreement with comments received that some decisions are programmatic in nature and should not be included in the Model Specifications. The Model Specifications are intended to apply to the performance of BAIID units, not the manner in which State and local jurisdictions conduct their programs (78 FR 26851). Consistent with this sentiment, NHTSA had intended to remove certain references, including those providing for the need for a service call in Test 8, but the agency inadvertently left them in this subsection.

This notice proposes to correct the third sentence, in the first paragraph under Test 8b (78 FR 26864), which currently reads: ''The BAIID must treat this test as a failed retest and prominently indicate the need for a service call.'' This notice proposes to revise this sentence as follows: ''The BAIID must treat this test as a failed retest and prominently alert the driver.''

Test 9. Tampering and Circumvention

One request for clarification related to elements of Test 9 in the Model Specifications, which test a BAIIDs ability to prevent tampering and circumvention.

d. Warmed Air Sample

The commenter asserted that ''a 12 oz Styrofoam coffee cup with a plastic lid can never get enough pressure. It would be better to mirror CNRC version of 0.5L PLASTIC cup with a lid.''

The purpose of Test 9d is to determine whether a warmed air sample (not from a person) can be pumped into a BAIID and cause an interlock-equipped vehicle to start. In the **Federal Register** notice published on May 8, 2013, NHTSA specified that a ''foam coffee cup'' with a ''plastic lid'' be used (78 FR 26864). However, the properties of the cup and lid are more important than the materials they are made from.

This notice proposes to clarify that the cup must be insulated, but it need not be constructed of Styrofoam; and that the lid must be secure, but it need not be constructed of plastic. This notice proposes to change the first sentence of the instructions for this test by providing, ''Prepare a 12-ounce insulated cup, fitted with a bubble tube inlet and a vent tube (rubber or tygon tubing), attached through a secure lid.''

f. Filtered 0.032 BrAC Sample

The commenter asserted that ''The paper tube called for does not work. You can typically not build up enough pressure in the paper tube to trigger a sample at all, meaning the test is very easy to pass. If it were changed to any readily available material, it would be more effective to testing for the ability of the filtering material itself to filter out the alcohol and not just the fact that there is not enough pressure.''

In the **Federal Register** notice published on May 8, 2013, Test 9f in the Model Specifications provided, ''Prepare a 1 to 2 inch diameter 3 to 5 inches long paper tube loosely packed with an active absorbent material . . . [and using] cotton plugs to retain the absorbent [material] in the paper tube.'' (78 FR 26864)

The purpose of this test is to determine whether an interlock-equipped vehicle would start if a person with alcohol in their system were to blow an air sample through a filter. NHTSA believes that using ''a 1 to 2 inch diameter 3 to 5 inches long paper tube loosely packed with an active absorbent material . . . [and using] cotton plugs to retain the absorbent [material] in the paper tube'', as

described in the Model Specifications, will permit a sufficient test under this section. To clarify, a cardboard tube can be used in lieu of thinner paper goods, and absorbent material can include charcoal, kitty litter or other materials that are readily available. Moreover, this test is not designed to determine the ability of any particular material to filter alcohol from an air sample. Rather, it is a test of the BAIID's ability to detect whether an air sample containing alcohol has been filtered to remove the alcohol.

Accordingly, this notice proposes to provide additional flexibility in the materials that may be used in conducting this test. It proposes to provide instead, ''Prepare a 1 to 2 inch diameter 3 to 5 inches long tube loosely packed with an active absorbent material. Use porous plugs (such as cotton) to retain the absorbent material in the tube.''

Test 10. Restart of Stalled Motor Vehicle

In the **Federal Register** notice published on May 8, 2013, Test 10 in the Model Specifications stated that a restart without breath sample in less than 3 minutes should allow the vehicle to start, but then it stated, ''Attempt to restart the ignition without a breath sample within 3 minutes . . . the vehicle must not start.'' (78 FR 26865) The agency received comments, stating that these provisions appear contradictory and are confusing.

This notice proposes to correct the Model Specifications as follows: ''Attempt to restart the engine without a breath sample in less than 3 minutes—the vehicle must start. Turn off the engine. Attempt to restart the engine without a breath sample 3 minutes or more after turning off the engine—the vehicle must not start.'' If trying to start the vehicle after 3 minutes, a breath sample would need to be provided.

Test 14. Radiofrequency Interference/ Electromagnetic Interference

Test 14 of the Model Specifications is entitled ''Radiofrequency Interference (RFI)/Electromagnetic Interference (EMI)''. It contains a series of tests to evaluate BAIID for radiofrequency and electromagnetic immunity and compatibility. These tests are based on standards that are commonly used in the industry for motor vehicles and motor vehicle equipment, including Society of Automotive Engineers (SAE) Surface Vehicle Standard J1113 series, Required Function Performance Status, as defined in Surface Vehicle Standard J113–1 for Class C devices and the International Special Committee on Radio Interference (CISPR), Subcommittee of International Electrotechnical Committee (IEC), CISPR 25.

In conducting its assessment of the RFI/EMI tests, NHTSA determined that some aspects of Test 14 required correction and/or clarification. This notice proposes a number of revisions to account for these issues.

a. Drive and Standby Modes

The Model Specifications provide that Test 14 ''must be performed while the BAIID is in the drive and standby modes.'' During our assessment, we observed no differences between the RFI/EMC test results obtained in standby (ready to blow) mode and the results obtained in drive mode. Therefore, testing in Drive mode appears to be unnecessary. For this reason, NHTSA proposes to revise the Model Specifications to provide that Test 14 need only ''be performed in standby mode.''

b. Frequency Range of Tests 14c. and 14f

The Model Specifications specifies the frequency range for some, but not all, tests to be performed under Test 14. In particular, the Model Specifications did not specify the frequency range for Test 14c (J1113–4 2004–08 Conducted Immunity—Bulk Current Injection (BCI) Method). Consistent with SAE Standards, this notice proposes to add that Test 14c should be performed from 1 MHz to 400 MHz.

Normally, the frequency ranges of Test 14c and Test 14f (J1113–21 2005–10 Immunity to Electromagnetic Fields) are run as companion tests. Together, they cover the entire frequency range of a device being tested. Accordingly, consistent with SAE Standards, this notice proposes to revise the Model Specification to provide that Test 14f should be performed from 400 MHz to 18 GHz. Combined with Test 14c, the entire frequency range of 1 MHz to 18 GHz would be covered.

c. Clarification of Conditions Under Test 14d, Pulse 5

The Model Specifications identified the final pulse under Test 14d as Pulse 5, but this pulse should have been identified as Pulse 5a. This notice proposes to make that correction. The parameters of the test will remain unchanged. It should continue to be conducted at Level 1, with 87 volts. As before, to conform to the test, a BAIID must achieve Status IV (no damage to function after disturbance is removed; dealer action may be required to return the function to normal operation after the disturbance is removed, *e.g.,* battery reset).

The agency encourages interested parties to carefully review this notice and the proposed revisions to the Model Specifications that are described herein, and to submit comments in the manner identified in the Addresses above.

Techical Corrections to Text of Model Specifications

For convenience and clarity, the full text of the Tests that are corrected are included below.

1. In the **Federal Register** of May 8, 2013, on page 26864, in column 3, Test 9e is corrected to read as follows:

Test 9. Tampering and Circumvention

* * * * *

e. Cooled 0.032 BrAC sample. Attach a 4 foot long tygon tube of 3/8 inch inside diameter which has been cooled to ice water temperature (0 °C/32 °F) to the inlet of the BAIID, then test at 0.032 BrAC. The vehicle must not start.

2. In the **Federal Register** of May 8, 2013, on page 26865, in column 1, the title for Test 11 is corrected to read as follows:

Test 11. Altitude

3. In the **Federal Register** of May 8, 2013, on page 26866, in column 1, Test 16 is corrected to read as follows:

Test 16. Data Integrity and Format

Complete all other tests before performing Test 16. Download the data from the interlock data logger and compare it to the data recorded for each test. Disconnect, then reconnect the power to the interlock data logger. Download the data again and compare it to the first data download. No lost or corrupted data is allowed. Check the data format (*i.e.,* date and time of event) to verify conformance with the sample format in Appendix B.

Proposed Changes to Text of Model Specifications

1. NHTSA proposes to revise the Model Specifications published in the **Federal Register** of May 8, 2013, on page 26864, in column 1, Test 8 to read as follows:

Test 8. Retest

If a BAIID includes a feature designed to detect whether the vehicle is moving, conduct Test 8 using a motor vehicle. If a BAIID does not include a feature designed to detect whether the vehicle is moving, conduct Test 8 using a motor vehicle or a bench test set-up that simulates the relevant functions of a motor vehicle.

a. Within an interval of 5 to 7 minutes after a vehicle successfully starts, using

a 0.000 g/dL BrAC test sample, and while the engine is still running, the BAIID must indicate that a second breath sample is required. Conduct Test 1b five times. The BAIID must treat this test as a passed retest all 5 times.

b. Within an interval of 5 to 7 minutes after a vehicle successfully starts, using a 0.000 g/dL BrAC test sample, and while the engine is still running, the BAIID must indicate that a second breath sample is required. Conduct Test 1c five times. The BAIID must treat this test as a failed retest and prominently alert the driver.

A failed retest must be identified as an alert condition and flagged on the interlock data logger. A missed retest must be flagged on the interlock data logger.

2. NHTSA proposes to revise the Model Specifications published in the **Federal Register** of May 8, 2013, on page 26864, in columns 2–3, Test 9d and Test 9f to read as follows:

Test 9. Tampering and Circumvention

* * * * *

d. *Warmed air sample.* Prepare a 12-ounce insulated cup fitted with a bubble tube inlet and a vent tube (rubber or tygon tubing), attached through a secure lid. Fill the cup with 8 ounces of water warmed to 36°C and attach the lid. Attach the vent tube to the BAIID and pass an air sample of at least 2 liters through the bubble tube into the heated water and thence into the BAIID. The flow rate must not be high enough to cause a mechanical transfer of water to the BAIID. The vehicle must not start.

* * * * *

f. *Filtered 0.032 BrAC sample.* Prepare a 1 to 2 inch diameter 3 to 5 inches long tube loosely packed with an active absorbent material. Use porous plugs (such as cotton) to retain the absorbent material in the tube. Pack the tube so that a person can easily blow 2 liters of air through the assembly within 5 seconds. Test the absorbent by passing a 2 liter 0.032 BrAC sample though the assembly within 5 seconds. If the air passing out of the BAIID is found to have a concentration of 0.006 BrAC or less, prepare 5 tubes packed in the same manner, fit separately to the BAIID and test at 0.032 BrAC. The vehicle must not start.

* * * * *

4. NHTSA proposes to revise the Model Specifications published in the **Federal Register** of May 8, 2013, on page 26865, in column 1, Test 10 to read as follows:

Test 10. Restart of Stalled Motor Vehicle

Conduct Test 10 using a motor vehicle.

Using a 0.000 g/dL BrAC sample, turn on the engine. Turn off the engine. Attempt to restart the ignition without a breath sample in less than 3 minutes—the vehicle must start. Turn off the engine. Attempt to restart the engine without a breath sample 3 minutes or more after turning off the engine—the vehicle must not start. Conduct Test 10 five times.

5. NHTSA proposes to revise Test 14 of the Model Specifications published in the **Federal Register** of May 8, 2013, beginning on page 26865, in column 1, to read as follows:

Test 14. Radiofrequency Interference (RFI)/Electromagnetic Interference (EMI)

The Society of Automotive Engineers (SAE) Surface Vehicle Standard J1113 series, Required Function Performance Status, as defined in Surface Vehicle Standard J1113–1 for Class C devices (devices essential to the operation or control of the vehicle), and the International Special Committee on Radio Interference (CISPR), Subcommittee of International Electrotechnical Committee (IEC), specifically CISPR 25, will be used to evaluate BAIID electromagnetic immunity and compatibility. The test severity levels are specified below. The tests must be performed while the BAIID is in standby mode.

* * * * *

c. J1113–4 2004–08 Conducted immunity, 1 MHz to 400 MHz—Bulk Current Injection (BCI) Method.

Level	Severity (volts, peak to peak)	Status
1	25 to 60	I
2	60 to 80	II
3	80 to 100	III
4	100	IV

d. *J1113–11* 2007–06 Immunity to Conducted Transients on Power Leads.

Pulse (12 v sys)	Level	Severity (volts)	Status
1	1	−25	I
	2	−50	II
	3	−75	II
	4	−100	IV
2a	1	25	I
	2	40	II
	3	50	II
	4	75	IV
2b	1	10	I
3a	1	−35	I
	2	−75	II
	3	−112	II
	4	−150	IV
3b	1	25	I
	2	50	II
	3	75	II
	4	100	IV
4	1	−4	I
	2	−5	II
	3	−6	II
	4	−7	IV
5a	1	87	IV

* * * * *

f. J1113–21 2005–10 Immunity to Electromagnetic Fields, 400 MHz to 18 GHz.

Severity (V/M)	Status
Up to 60	I
60–80	II
80–100	III
100–150	IV

(Authority: 23 U.S.C. 403; 49 CFR 1.95; 49 CFR Part 501)

Dated: March 25, 2015.

Jeffrey Michael,

Associate Administrator for the Office of Research and Program Development, National Highway Traffic Safety Administration.

[FR Doc. 2015–07161 Filed 3–27–15; 8:45 a.m.]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2012–0087]

Advisory Committee for Aviation Consumer Protection

AGENCY: Office of the Secretary (OST), Department of Transportation (DOT).

ACTION: Notice of seventh meeting of advisory committee.

SUMMARY: This notice announces the seventh meeting of the Advisory Committee for Aviation Consumer Protection.

DATES: The seventh meeting of the advisory committee is scheduled for April 14, 2015, from 9:00 a.m. to 4:00 p.m., Eastern Time.

ADDRESSES: The meeting will be held in the Media Center (located on the lobby level of the West Building) at the U.S. Department of Transportation (DOT) headquarters, 1200 New Jersey Avenue SE., Washington, DC. Attendance is open to the public up to the room's

capacity of 100 attendees. Since space is limited and access to the DOT headquarters building is controlled for security purposes, any member of the general public who plans to attend this meeting must notify the registration contact identified below no later than April 7, 2015.

FOR FURTHER INFORMATION CONTACT: To register to attend the meeting, please contact Amy Przybyla, Research Analyst, CENTRA Technology, Inc., *przybylaa@centratechnology.com;* 703–894–6962. For other information please contact Kathleen Blank Riether, Senior Attorney, Office of Aviation Enforcement and Proceedings, *kathleen.blankriether@dot.gov;* U.S. Department of Transportation, 1200 New Jersey Ave. SE., Washington, DC 20590; 202–366–9342 (phone), 202–366–5944 (fax).

SUPPLEMENTARY INFORMATION: On May 24, 2012, the Secretary, as mandated by Section 411 of the FAA Modernization and Reform Act of 2012 (Pub. L. 112–95, 126 Stat. 11 (2012)), established the Advisory Committee on Aviation Consumer Protection. The committee's charter, drafted in accordance with the Federal Advisory Committee Act, as amended, 5 U.S.C. App. 2, sets forth policies for the operation of the advisory committee and is available on the Department's Web site at *http://www.facadatabase.gov/committee/charters.aspx?cid=2448&aid=47.*

The seventh meeting of the committee is scheduled for Tuesday, April 14, 2015, from 9:00 a.m. to 4:00 p.m. Eastern Time in the Media Center at the DOT headquarters, 1200 New Jersey Avenue SE., Washington, DC 20590. At the meeting, the issues that will be discussed are space allocated per passenger on the aircraft and airlines' frequent flyer programs.

As announced in the notices of prior meetings of the committee, the meeting will be open to the public, and, time permitting, comments by members of the public are invited. Attendance will necessarily be limited by the size of the meeting room (maximum 100 attendees). Since space is limited and access to the DOT headquarters building is controlled for security purposes, we ask that any member of the general public who plans to attend the seventh meeting notify the registration contact noted above no later than April 7, 2015. Additionally, DOT will stream the event live on the Internet at *www.dot.gov/airconsumer/ACACP.*

Members of the public may present written comments at any time. The docket number referenced above (DOT–OST–2012–0087, available at *https://www.regulations.gov*) has been established for committee documents including any written comments that may be filed. At the discretion of the Chairperson and time permitting, after completion of the planned agenda, individual members of the public may provide oral comments. Any oral comments presented must be limited to the objectives of the committee and will be limited to five (5) minutes per person. Individual members of the public who wish to present oral comments must notify the Department of Transportation contact noted above via email that they wish to attend and present oral comments no later than April 7, 2015.

Persons with a disability who plan to attend the meeting and require special accommodations, such as an interpreter for the hearing impaired, should notify the registration contact noted above no later than April 7, 2015.

Notice of this meeting is being provided in accordance with the Federal Advisory Committee Act and the General Services Administration regulations covering management of Federal advisory committees.

(41 CFR part 102–3.)

Issued in Washington, DC, on the 25th of March, 2015.

Blane A. Workie,

Assistant General Counsel for Aviation Enforcement & Proceedings, U.S. Department of Transportation.

[FR Doc. 2015–07292 Filed 3–27–15; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2015–0021]

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 of the Code of Federal Regulations (CFR), this document provides the public notice that by a document dated November 20, 2014, the Transportation Technology Center (TTCI) has petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR 231.136(c)(4) and 231.126(c)(4). FRA assigned the petition Docket Number FRA–2015–0021.

Industry efforts are underway to develop industry standards for natural gas fuel tenders (NGFT) as fuel sources for locomotives. FRA has provided funding for a program to complement work conducted by the Association of American Railroads (AAR) NGFT Technical Advisory Group (TAG) in developing industry standards for NGFT tenders. This effort is focused on documenting (measuring and analyzing) the worst-case displacement environment between a common line-haul locomotive and a trailing vehicle (simulating a fuel tender).

This petition for a temporary waiver has been filed so that a test project can be conducted to measure and an understanding can be had of the tri-axial displacement environment of interconnections (*e.g.,* gas, cooling system loop, electrical, air, etc.) between the locomotive and adjacent tender vehicle during normal full-scale freight train operations in revenue service. This waiver also serves to give notice that the instrumentation brackets will be mounted to and partially obstruct the safety appliances on the locomotive and box car. The safety appliances affected will be the A-end end platform and the A-end handhold on the box car, and, in addition, a test fixture bracket will be attached to the uprights that secure horizontal handholds on the rear end of the locomotive. The test program outlined in the petition includes measurement of relative longitudinal, lateral, and vertical displacements and accelerations between the locomotive and simulated fuel tender. Data gathered will provide input for testing future fuel transfer components (*e.g.,* hoses, wires, and connectors for gas/heat exchange fluids/electrical power/control) planned for use on the next generation of NGFT vehicles.

Canadian National Railway (CN) is supplying the locomotive and high-cube box car for this testing. The locomotive's long hood end will be connected to and leading the box car's A-end. The intent is for both to be used throughout the testing from Chicago, IL, to Memphis, TN, and back. The requested duration of the waiver is to allow the testing from Chicago, IL, to Memphis, TN, and back to be completed. A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC, 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a

hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (*e.g.,* Waiver Petition Docket Number FRA–2015–0021) and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Communications received within 45 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.* See also *http://www.regulations.gov/#!privacyNotice* for the privacy notice of regulations.gov or interested parties may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477).

Issued in Washington, DC, on March 24, 2015.

Ron Hynes,

Director, Office of Technical Oversight.

[FR Doc. 2015–07102 Filed 3–27–15; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2015–0020]

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System

In accordance with Part 235 of Title 49 of the Code of Federal Regulations (CFR) and 49 U.S.C. 20502(a), this document provides the public notice that by a document dated February 18, 2015, the Union Pacific Railroad Company (UP) petitioned the Federal Railroad Administration (FRA) seeking approval for the discontinuance or modification of a signal system. FRA assigned the petition Docket Number FRA–2015–0020.

Applicants: Union Pacific Railroad Company, Mr. Neal Hathaway, AVP Engineering—Signal, 1400 Douglas Street, MS 0910, Omaha, NE 68179.

UP seeks approval of the discontinuance of the coded track circuits on the siding between Control Point (CP) W045, at Milepost (MP) 45.30. and CP W047 MP 47.20, on the Greely Subdivision at LaSalle, CO. The diverging yellow and flashing yellow aspects will be retired from the B head of the W signal at CP W047, and the B head of the E signal at CP W045.

The purpose of the discontinuance is to facilitate the large number of switching operations that take place in the siding.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulatons.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (*e.g.,* Waiver Petition Docket Number FRA–2015–0020) and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Communications received by May 14, 2015 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov*, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.* See also *http://www.regulations.gov/#!privacyNotice* for the privacy notice of regulations.gov or interested parties may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477).

Issued in Washington, DC, on March 24, 2015.

Ron Hynes,

Director, Office of Technical Oversight.

[FR Doc. 2015–07099 Filed 3–27–15; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA 2015–0007–N–5]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration, DOT.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and its implementing regulations, the Federal Railroad Administration (FRA) hereby announces that it is seeking an extension of the following currently

approved information collection activities. On March 13, 2015, FRA issued its ''Railworthiness Directive Under 49 CFR 180.509 for Railroad Tank Cars Equipped With Certain McKenzie Valve & Machining LLC Valves'' and published this Directive in the **Federal Register** on March 18, 2015. *See* 80 FR 14027. Also, on March 18, 2015, FRA published a Notice in the **Federal Register** requesting immediate Emergency Clearance Processing from the Office of Management and Budget (OMB) for the information collection associated with its Railworthiness Directive Notice No. 1. *See* 80 FR 14238. On March 19, 2015, OMB granted FRA's request for Emergency Clearance for its Railworthiness Directive Notice No. 1. The information collection activities associated with FRA's Railworthiness Directive Notice No. 1 received a six-month approval. FRA now seeks a regular clearance (extension of the current approval for three years) while tank car owners possessing the thousands of tank cars utilizing these problematic unapproved valves have them removed and replaced with approved valves. FRA has issued this Railworthiness Directive (Directive) to all owners of tank cars used to transport hazardous materials within the United States to ensure they identify and appropriately remove and replace these valves with approved valves consistent with Federal regulations.

Before submitting these information collection requirements for clearance by the Office of Management and Budget (OMB), FRA is soliciting public comment on specific aspects of the activities identified below.

DATES: Comments must be received no later than May 29, 2015.

ADDRESSES: Submit written comments on any or all of the following proposed activities by mail to either: Mr. Robert Brogan, Office of Safety, Planning and Evaluation Division, RRS–21, Federal Railroad Administration, 1200 New Jersey Ave. SE., Mail Stop 17, Washington, DC 20590, or Ms. Kimberly Toone, Office of Information Technology, RAD–20, Federal Railroad Administration, 1200 New Jersey Ave. SE., Mail Stop 35, Washington, DC 20590. Commenters requesting FRA to acknowledge receipt of their respective comments must include a self-addressed stamped postcard stating, ''Comments on OMB control number 2130–0606.'' Alternatively, comments may be transmitted via facsimile to (202) 493–6216 or (202) 493–6497, or via email to Mr. Brogan at *Robert.Brogan@dot.gov,* or to Ms. Toone at *Kim.Toone@dot.gov.* Please refer to the assigned OMB control number in any correspondence submitted. FRA will summarize comments received in response to this notice in a subsequent notice and include them in its information collection submission to OMB for approval.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Brogan, Office of Planning and Evaluation Division, RRS–21, Federal Railroad Administration, 1200 New Jersey Ave. SE., Mail Stop 17, Washington, DC 20590 (telephone: (202) 493–6292) or Ms. Kimberly Toone, Office of Information Technology, RAD–20, Federal Railroad Administration, 1200 New Jersey Ave. SE., Mail Stop 35, Washington, DC 20590 (telephone: (202) 493–6132). (These telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act of 1995 (PRA), Public Law 104–13, sec. 2, 109 Stat. 163 (1995) (codified as revised at 44 U.S.C. 3501–3520), and its implementing regulations, 5 CFR part 1320, require Federal agencies to provide 60-days notice to the public for comment on information collection activities before seeking approval for reinstatement or renewal by OMB. 44 U.S.C. 3506(c)(2)(A); 5 CFR 1320.8(d)(1), 1320.10(e)(1), 1320.12(a). Specifically, FRA invites interested respondents to comment on the following summary of proposed information collection activities regarding (i) whether the information collection activities are necessary for FRA to properly execute its functions, including whether the activities will have practical utility; (ii) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (iii) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (iv) ways for FRA to minimize the burden of information collection activities on the public by automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.,* permitting electronic submission of responses). *See* 44 U.S.C. 3506(c)(2)(A)(I)–(iv); 5 CFR 1320.8(d)(1)(I)–(iv). FRA believes that soliciting public comment will promote its efforts to reduce the administrative and paperwork burdens associated with the collection of information mandated by Federal regulations. In summary, FRA reasons that comments received will advance three objectives: (i) Reduce reporting burdens; (ii) ensure that it organizes information collection requirements in a ''user friendly'' format to improve the use of such information; and (iii) accurately assess the resources expended to retrieve and produce information requested. *See* 44 U.S.C. 3501.

Below are brief summaries of three currently approved information collection activities that FRA will submit for clearance by OMB as required under the Paperwork Reduction Act:

Title: Railworthiness Directive Notice No. 1.

OMB Control Number: 2130–0606.

Abstract: Recent FRA investigations identified several railroad tank cars transporting hazardous materials and leaking small quantities of product from the cars' liquid lines. FRA's investigation revealed that the liquid lines of the leaking tank cars were equipped with a certain type of 3-inch ball valve marketed and sold by McKenzie Valve & Machining LLC (McKenzie) (formerly McKenzie Valve & Machining Company), an affiliate company of Union Tank Car Company (UTLX). FRA further found certain closure plugs installed on the 3-inch valves cause mechanical damage to the valves, which leads to the destruction of the valves' seal integrity and that the 3-inch valves, as well as similarly-designed 1-inch and 2-inch valves provided by this manufacturer are not approved for use on tank cars.

Form Number(s): N/A.

Affected Public: Businesses.

Frequency of Submission: One-time; on occasion.

Respondent Universe: 100 Tank Car Owners.

REPORTING BURDEN

Railworthiness directive notice No. 1: Requirements	Respondent universe	Total annual responses	Average time per response	Total annual burden hours
I. Identification of RR tank cars equipped with McKenzie valves & document providing reporting mark and number of each car so equipped and type of valve to FRA.	100 Tank Car Owners (15,000 affected tank cars).	200 identifications/reports.	2 hours	400
—Record of Inspection Date and Location and Results of Inspection.	100 Tank Car Owners (15,000 affected tank cars).	200 records	30 minutes	100

Total Estimated Responses: 400.

Total Estimated Annual Burden: 500 hours.

Status: Regular Review.

Pursuant to 44 U.S.C. 3507(a) and 5 CFR 1320.5(b), 1320.8(b)(3)(vi), FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Issued in Washington, DC, on March 25, 2015.

Rebecca Pennington,

Chief Financial Officer.

[FR Doc. 2015–07185 Filed 3–27–15; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2014–0120]

Petition for Waiver of Compliance

In accordance with part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that by a document dated November 7, 2014, the Port Authority Trans-Hudson Corporation (PATH) has petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 236—Rules, Standards, and Instructions Governing the Installation, Inspection, Maintenance, and Repair of Signal and Train Control Systems, Devices, and Appliances. FRA assigned the petition Docket Number FRA–2014–0120.

This request is for an extension of time from the requirements of 49 CFR 236.108(a), *Insulation resistance tests, wires in trunking, and cables,* and the related 49 CFR 236.110, *Results of tests.* PATH is seeking to extend the test time interval from 10 years to 13 years for the approximately 840 local and express cables involved. These cables would still be subject to all other rules and requirements under 49 CFR part 236, subpart A.

The referenced cables are scheduled to be replaced within the next 3 years under the PATH Automatic Train Control signal system replacement project. Under this project, which started in 2010, PATH is installing a communications-based train control/Positive Train Control system in which all of the existing relay-based interlocking and automatic block signal control equipment, internal bungalow wiring, and cabling from the bungalow to the field devices is being replaced. The requested extension of time will aid in the acceleration plans for the new system as PATH staff who will be relieved from cable testing requirements will be used for the installation of the new system.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Communications received by May 14, 2015 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.* See also *http://www.regulations.gov/#!privacyNotice* for the privacy notice of regulations.gov or interested parties may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477).

Issued in Washington, DC, on March 24, 2015.

Ron Hynes,

Director, Office of Technical Oversight.

[FR Doc. 2015–07098 Filed 3–27–15; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2008–0161]

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that by a document dated

December 16, 2014, the Alaska Railroad Corporation (ARRC) has petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 238, Passenger Equipment Safety Standards. FRA assigned the petition Docket Number FRA–2008–0161.

The ARRC, a Class II railroad, petitioned FRA for a waiver of compliance from certain provisions of 49 CFR part 238, as prescribed by 49 CFR 238.303(c), *Exterior calendar day inspection of passenger equipment,* and 238.313(d), *Class I brake test,* for one set of conventional passenger equipment. Specifically, this waiver request applies to the seasonal Hurricane Turn passenger train. This service is operated during the months of May through September, 4 days a week with one round trip per day, between Talkeetna, AK, Milepost (MP) 226, and Hurricane Gulch Bridge, AK, MP 284. The passenger equipment utilized for this train consists of two passenger coaches, one baggage car, and two locomotives (used in push/pull service). This train provides ''flag stop'' service to residents and visitors to an area that has no road access.

The ARRC maintains mechanical facilities in Fairbanks, AK, MP 470, and Anchorage, AK, MP 114, where qualified maintenance employees are headquartered. The equipment is stored overnight at Talkeetna during the work week, and may be moved to Anchorage during rest days for cleaning, supplies, and servicing. FRA requires a qualified maintenance person (QMP) to conduct the daily exterior inspection and the Class I initial terminal airbrake inspection on each day the equipment is used. This requires the ARRC to assign a QMP to Talkeetna, where there is not enough work to support a position, or have an employee travel 224 miles (round trip) each day from Anchorage.

The ARRC requests that a QMP be authorized to complete the required daily exterior and airbrake inspections at Talkeetna at least once a week, during those months when equipment is stationed there. The equipment may be moved to Anchorage, or a mechanical department road truck will travel to Talkeetna to have a QMP conduct the required inspections. Talkeetna is the only location that this relief is sought. Qualified persons, as defined in 49 CFR 238.5, *Definitions,* may perform the exterior calendar-day inspection and Class I brake test on all other days, provided they are trained, qualified, and designated to perform such functions in accordance with 49 CFR 238.109, *Training, qualification, and designation program.*

The ARRC has safely operated this equipment under the conditions set by FRA's Railroad Safety Board since 2009, under Docket Number FRA–2008–0161. Due to economic growth, the ARRC is looking to expand the seasonal Hurricane Turn passenger train service and equipment. The ARRC has petitioned FRA to modify the current waiver of compliance to increase the service from 4 to 5 days a week and to increase the passenger train consist from two passenger coaches to three passenger coaches.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by May 14, 2015 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.* See also *http://www.regulations.gov/#!privacyNotice* for the privacy notice of regulations.gov.

Issued in Washington, DC, on March 24, 2015.

Ron Hynes,

Director, Office of Technical Oversight.

[FR Doc. 2015–07100 Filed 3–27–15; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Women Veterans; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2., that the Advisory Committee on Women Veterans will meet on May 19–21, 2015, in Room 930, at VA Central Office, 810 Vermont Avenue NW., Washington, DC, from 8:30 until 4:00 p.m. on Tuesday and Thursday and end at 3:00 p.m. on Wednesday. The meeting is open to the public.

The purpose of the Committee is to advise the Secretary of Veterans Affairs regarding the needs of women Veterans with respect to health care, rehabilitation, compensation, outreach, and other programs and activities administered by VA designed to meet such needs. The Committee makes recommendations to the Secretary regarding such programs and activities.

The agenda will include updates from the Veterans Health Administration, the Veterans Benefits Administration, and Staff Offices, as well as updates on recommendations from the 2012 and 2014 Reports of the Advisory Committee on Women Veterans.

No time will be allocated at this meeting for receiving oral presentations from the public. Interested parties should provide written comments for review by the Committee to Ms. Shannon L. Middleton, VA, Center for Women Veterans (00W), 810 Vermont Avenue NW., Washington, DC 20420, or email at *00W@mail.va.gov,* or fax to (202) 273–7092. Any member of the public who wishes to attend the meeting or wants additional information should contact Ms. Middleton at (202) 461–

6193. Because the meeting will be in a Government building, anyone attending must be prepared to show a valid photo I.D. Please allow 15 minutes before the meeting begins for this process.

Dated: March 25, 2015.

Jelessa Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2015–07179 Filed 3–27–15; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Geriatrics and Gerontology Advisory Committee; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that a meeting of the Geriatrics and Gerontology Advisory Committee will be held on April 28–29, 2015, in Room 530 at VA, 810 Vermont Avenue NW., Washington, DC. On April 28, the session will begin at 8:30 a.m. and end at 5:00 p.m. On April 29, the session will begin at 8:00 a.m. and end at 12 noon. This meeting is open to the public.

The purpose of the Committee is to provide advice to the Secretary of VA and the Under Secretary for Health on all matters pertaining to geriatrics and gerontology. The Committee assesses the capability of VA health care facilities and programs to meet the medical, psychological, and social needs of older Veterans and evaluates VA programs designated as Geriatric Research, Education, and Clinical Centers.

The meeting will feature presentations and discussions on VA's geriatrics and extended care programs, aging research activities, updates on VA's employee staff working in the area of geriatrics (to include training, recruitment and retention approaches), Veterans Health Administration (VHA) strategic planning activities in geriatrics and extended care, recent VHA efforts regarding dementia and program advances in palliative care, and performance and oversight of VA Geriatric Research, Education, and Clinical Centers.

No time will be allocated at this meeting for receiving oral presentations from the public. Interested parties should provide written comments for review by the Committee to Mrs. Marcia Holt-Delaney, Program Analyst, Geriatrics and Extended Care Services (10P4G), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, or via email at *Marcia.Holt-Delaney@va.gov.* Individuals who wish to attend the meeting should contact Mrs. Holt-Delaney at (202) 461–6769.

Rebecca Schiller,

Committee Management Officer.

[FR Doc. 2015–07165 Filed 3–27–15; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Research Advisory Committee on Gulf War Veterans' Illnesses; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C App.2 that the Research Advisory Committee on Gulf War Veterans' Illnesses will meet on April 20 and 21, 2015, in Washington, DC. The meeting will be held in room 230, 810 Vermont Avenue NW., Washington, DC, from 9:00 a.m. until 5:15 p.m. on Monday, April 20, and from 9:00 a.m. until 1:00 p.m. on Tuesday, April 21. All sessions will be open to the public, and for interested parties who cannot attend in person, there is a toll-free telephone number (800–767–1750; access code 56978#).

The purpose of the Committee is to provide advice and make recommendations to the Secretary of Veterans Affairs on proposed research studies, research plans, and research strategies relating to the health consequences of military service in the Southwest Asia theater of operations during the Gulf War in 1990–1991.

The Committee will review VA program activities related to Gulf War Veterans' illnesses, and updates on relevant scientific research published since the last Committee meeting. Presentations on April 20 will include updates on the VA Gulf War Research Program, followed by research presentations on a treatment for pain, neuroimaging in Gulf War Veterans, and drug trials in animal models. The Committee will devote April 21 to a discussion of Committee business and activities.

The meeting will include time reserved for public comments on both days in the afternoon. A sign-up sheet for 5-minute comments will be available at the meeting. Individuals who wish to address the Committee may submit a 1–2 page summary of their comments for inclusion in the official meeting record. Members of the public may also submit written statements for the Committee's review to Dr. Roberta White at *rwhite@bu.edu.*

Because the meeting is being held in a government building, a photo I.D. must be presented as part of the clearance process. Therefore, any person attending should allow an additional 15 minutes before the meeting begins to clear security. Any member of the public seeking additional information should contact Dr. White, Scientific Director, at (617) 638–4620 or Dr. Victor Kalasinsky, Designated Federal Officer, at (202) 443–5682.

Dated: March 25, 2015.

Rebecca Schiller,

Committee Management Officer.

[FR Doc. 2015–07169 Filed 3–27–15; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Voluntary Service National Advisory Committee; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that the annual meeting of the Department of Veterans Affairs Voluntary Service (VAVS) National Advisory Committee (NAC) will be held April 22–24, 2015, at the Albuquerque Marriott, 2101 Louisiana Boulevard NE., Albuquerque, New Mexico. On April 22, the meeting will begin at 8:00 a.m. and end at 11:30 a.m. On April 23–24, 2015, the meetings will begin at 8:30 a.m. and end at 4:30 p.m. on April 23, and end at 3:45 p.m. on April 24. The meeting is open to the public.

The Committee, composed of fifty-four national voluntary organizations, advises the Secretary, through the Under Secretary for Health, on the coordination and promotion of volunteer activities within VA facilities. The purposes of this meeting are: To provide for Committee review of volunteer policies and procedures; to accommodate full and open communications between organization representatives and the Voluntary Service Office and field staff; to provide educational opportunities geared towards improving volunteer programs with special emphasis on methods to recruit, retain, place, motivate, and recognize volunteers; and to provide Committee recommendations. The April 22 session will include a National Executive Committee Meeting, Health and Information Fair, and VAVS Representative and Deputy Representative training session. The April 23 business session will include welcoming remarks from local officials, and remarks by VA officials on new and ongoing VA initiatives. The recipients of

the American Spirit Recruitment Awards, VAVS Award for Excellence, and the NAC male and female Volunteer of the Year awards will be recognized. Educational workshops will be held in the afternoon and will focus on cultural competency, leadership through service, MyHealthe Vet, VA's personal health record, and communications and community engagement. On April 24, the morning business session will include subcommittee reports, the Voluntary Service Report, and the Veterans Health Administration Update. The educational workshops will be repeated in the afternoon. No time will be allocated at this meeting for receiving oral presentations from the public. However, the public may submit written statements for the Committee's review to Ms. Sabrina C. Clark, Designated Federal Officer, Voluntary Service Office (10B2A), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, or by email at *Sabrina.Clark@va.gov.* Any member of the public wishing to attend the meeting or seeking additional information should contact Ms. Clark at (202) 461–7300.

By direction of the Secretary.

Jelessa Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2015–07180 Filed 3–27–15; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare and Medicaid Services

42 CFR Part 495

Office of the Secretary

45 CFR Part 170

Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3; 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 495

[CMS–3310–P]

RIN 0938–AS26

Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This Stage 3 proposed rule would specify the meaningful use criteria that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet in order to qualify for Medicare and Medicaid electronic health record (EHR) incentive payments and avoid downward payment adjustments under Medicare for Stage 3 of the EHR Incentive Programs. It would continue to encourage electronic submission of clinical quality measure (CQM) data for all providers where feasible in 2017, propose to require the electronic submission of CQMs where feasible in 2018, and establish requirements to transition the program to a single stage for meaningful use. Finally, this Stage 3 proposed rule would also change the EHR reporting period so that all providers would report under a full calendar year timeline with a limited exception under the Medicaid EHR Incentive Program for providers demonstrating meaningful use for the first time. These changes together support our broader efforts to increase simplicity and flexibility in the program while driving interoperability and a focus on patient outcomes in the meaningful use program.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 29, 2015.

ADDRESSES: In commenting, please refer to file code CMS–3310–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–3310–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3310–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:
Elizabeth Holland, (410) 786–1309, Medicare EHR Incentive Program and Medicare payment adjustment
Elisabeth Myers (CMS), (410) 786–4751, Medicare EHR Incentive Program
Thomas Romano (CMS), (410) 786–0465, Medicaid EHR Incentive Program
Ed Howard (CMS), (410) 786–6368, Medicare Advantage
Deborah Krauss (CMS), (410) 786–5264, clinical quality measures
Alesia Hovatter (CMS), (410) 786–6861, clinical quality measures
Elise Sweeney Anthony (ONC), (202) 475–2485, certification definition

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will 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.

Acronyms

API Application-Program Interface
ARRA American Recovery and Reinvestment Act of 2009
AAC Average Allowable Cost (of certified EHR Technology)
ACO Accountable Care Organization
AIU Adopt, Implement, Upgrade (certified EHR Technology)
CAH Critical Access Hospitals
CAHPS Consumer Assessment of Healthcare Providers and Systems
CCN CMS Certification Number
CDC Centers for Disease Control
CEHRT Certified Electronic Health Record Technology
CFR Code of Federal Regulations
CHIP Children's Health Insurance Program
CHIPRA Children's Health Insurance Program Reauthorization Act of 2009
CMS Centers for Medicare and Medicaid Services
CPOE Computerized Physician Order Entry
CQM Clinical Quality Measure
CY Calendar Year
EHR Electronic Health Record
EP Eligible Professional
EPO Exclusive Provider Organization
FACA Federal Advisory Committee Act
FFP Federal Financial Participation
FFY Federal Fiscal Year
FFS Fee-for-Service
FQHC Federally Qualified Health Center
FTE Full Time Equivalent
FY Fiscal Year
HEDIS Healthcare Effectiveness Data and Information Set
HHS Department of Health and Human Services
HIE Health Information Exchange

HIT Health Information Technology
HITPC Health Information Technology Policy Committee
HIPAA Health Insurance Portability and Accountability Act of 1996
HITECH Health Information Technology for Economic and Clinical Health Act
HMO Health Maintenance Organization
HOS Health Outcomes Survey
HPSA Health Professional Shortage Area
HRSA Health Resources and Services Administration
IAPD Implementation Advanced Planning Document
ICR Information Collection Requirement
IHS Indian Health Service
IPA Independent Practice Association
IPPS Inpatient Prospective Payment System
IQR Inpatient Quality Reporting
IT Information Technology
MA Medicare Advantage
MAC Medicare Administrative Contractor
MCO Managed Care Organization
MITA Medicaid Information Technology Architecture
MMIS Medicaid Management Information Systems
MSA Medical Savings Account
MU Meaningful Use
NAAC Net Average Allowable Cost (of certified EHR Technology)
NCQA National Committee for Quality Assurance
NCVHS National Committee on Vital and Health Statistics
NPI National Provider Identifier
NQF National Quality Forum
ONC Office of the National Coordinator for Health Information Technology
PAHP Prepaid Ambulatory Health Plan
PAPD Planning Advanced Planning Document
PFFS Private Fee-for-Service
PHO Physician Hospital Organization
PHS Public Health Service
PHSA Public Health Service Act
PIHP Prepaid Inpatient Health Plan
POS Place of Service
PPO Preferred Provider Organization
PQRS Physician Quality Reporting System
PHI Protected Health Information
PSO Provider Sponsored Organization
RHC Rural Health Clinic
RPPO Regional Preferred Provider Organization
SAMHSA Substance Abuse and Mental Health Services Administration
SMHP State Medicaid Health Information Technology Plan
TIN Tax Identification Number

I. Executive Summary and Background

A. Executive Summary

1. Purpose of Regulatory Action

a. Need for Regulatory Action

In this proposed rule, we specify the policies that would be applicable for Stage 3 of the Medicare and Medicaid EHR Incentive Programs. Under Stage 3, we are proposing a set of requirements that EPs, eligible hospitals, and CAHs must achieve in order to meet meaningful use, qualify for incentive payments under the Medicare and Medicaid EHR Incentive Programs, and avoid downward payment adjustments under Medicare. These Stage 3 requirements focus on the advanced use of certified EHR technology (CEHRT) to promote health information exchange and improved outcomes for patients.

Stage 3 of meaningful use is expected to be the final stage and would incorporate portions of the prior stages into its requirements. In addition, following a proposed optional year in 2017, beginning in 2018 all providers would report on the same definition of meaningful use at the Stage 3 level regardless of their prior participation, moving all participants in the EHR Incentive Programs to a single stage of meaningful use in 2018. The incorporation of the requirements into one stage for all providers is intended to respond to stakeholder input regarding the complexity of the program, the success of certain measures which are part of the meaningful use program to date, and the need to set a long-term, sustainable foundation based on a consolidated set of key advanced use objectives for the Medicare and Medicaid EHR Incentive Programs.

In addition, we propose changes to the EHR reporting period, timelines, and structure of the Medicare and Medicaid EHR Incentive Programs. We believe these changes would provide a flexible, clear framework to reduce provider burden, streamline reporting, and ensure future sustainability of the Medicare and Medicaid EHR Incentive Programs. These changes together lay a foundation for our broader efforts to support interoperability and quality initiatives focused on improving patient outcomes.

b. Legal Authority for the Regulatory Action

The American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5) amended Titles XVIII and XIX of the Social Security Act (the Act) to authorize incentive payments to EPs, eligible hospitals, and CAHs, and Medicare Advantage (MA) organizations to promote the adoption and meaningful use of Certified Electronic Health Record Technology (CEHRT). Sections 1848(o), 1853(l) and (m), 1886(n), and 1814(l) of the Act provide the statutory basis for the Medicare incentive payments made to meaningful EHR users. These statutory provisions govern EPs, MA organizations (for certain qualifying EPs and hospitals that meaningfully use CEHRT), subsection (d) hospitals and critical access hospitals (CAHs), respectively. Sections 1848(a)(7), 1853(l) and (m), 1886(b)(3)(B), and 1814(l) of the Act also establish downward payment adjustments, beginning with calendar or fiscal year (FY) 2015, for EPs, MA organizations, subsection (d) hospitals, and CAHs that are not meaningful users of CEHRT for certain associated reporting periods. Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for Medicaid incentive payments. (There are no payment adjustments under Medicaid). (For a more detailed explanation of the statutory basis for the EHR incentive payments, see the July 28, 2010 Stage 1 final rule titled, ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule'' (75 FR 44316 through 44317)).

2. Summary of Major Provisions

a. Meaningful Use in 2017 and Subsequent Years

The Stage 1 final rule sets the foundation for the Medicare and Medicaid EHR Incentive Programs by establishing requirements for the electronic capture of clinical data, including providing patients with electronic copies of their health information. We outlined Stage 1 meaningful use criteria, and finalized core and menu objectives for EPs, eligible hospitals, and CAHs. (For a full discussion of Stage 1 of meaningful use, we refer readers to the Stage 1 final rule (75 FR 44313 through 44588).)

In the September 4, 2012 Stage 2 final rule (77 FR 53967 through 54162), we focused on the next step after the foundation of data capture in Stage 1, the exchange of that essential health data among health care providers and patients to improve care coordination. To this end, we maintained the same core-menu structure for several finalized Stage 1 core and menu objectives. We finalized that EPs must meet the measure for or qualify for an exclusion to 17 core objectives and 3 of 6 menu objectives. We finalized that eligible hospitals and CAHs must meet the measure or qualify for an exclusion to 16 core objectives and 3 of 6 menu objectives. We combined several Stage 1 measures included into Stage 2. With the experience providers gained from the Stage 1 final rule, we also increased functional objective measure thresholds in Stage 2 to increase efficiency, effectiveness, and flexibility. We also finalized a set of clinical quality measures (CQMs) for all providers participating in any stage of the program to report to CMS beginning in 2014. (For a full discussion of the meaningful use objectives and measures, and the CQMs we finalized under Stage 2, we refer

readers to the Stage 2 final rule at 77 FR 53967 through 54162.)

In this Stage 3 proposed rule, we build on the groundwork established in the Stage 1 and Stage 2 final rules, including continuing our goal started under Stage 2 to increase interoperable health data sharing among providers. In addition, this Stage 3 proposed rule would also focus on the advanced use of EHR technology to promote improved patient outcomes and health information exchange. We also propose to continue improving program efficiency, effectiveness, and flexibility by making changes to the Medicare and Medicaid EHR Incentive Programs that simplify reporting requirements and reduce program complexity. These changes proposed respond to comments received in earlier rulemaking that expressed confusion and concerns regarding increased reporting burden related to the number of program requirements, the multiple stages of program participation, and the timing of EHR reporting periods. In order to address these stakeholder concerns, one significant change we propose for Stage 3 includes establishing a single set of objectives and measures (tailored to EP or eligible hospital/CAH) to meet the definition of meaningful use. This new, streamlined definition of meaningful use proposed for Stage 3 would be optional for any provider who chooses to attest to these objectives and measures for an EHR reporting period in 2017; and would be required for all eligible providers—regardless of prior participation in the EHR Incentive Program—for an EHR reporting period in 2018 and subsequent years.

In addition to reducing program complexity, the Stage 3 proposed rule would further support efforts to align the EHR Incentive Programs with other CMS quality reporting programs that use certified EHR technology, such as the Hospital Inpatient Quality Reporting (IQR) and Physician Quality Reporting System (PQRS) programs, as well as continue alignment across care settings for providers demonstrating meaningful use. This alignment would both reduce provider burden associated with reporting on multiple CMS programs and enhance CMS operational efficiency. The Stage 3 proposed rule and ONC's 2015 Edition of Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications (hereinafter referenced as the ''2015 Edition proposed rule'') published elsewhere in this edition of the **Federal Register** would also continue to support the privacy and security of patient health information within certified health IT.

b. Meaningful Use Requirements, Objectives and Measures for 2017 and Subsequent Years

Under this Stage 3 proposed rule, with the exception of Medicaid providers in their first year of demonstrating meaningful use as detailed in section II.F.1. of this proposed rule, all providers (EPs, eligible hospitals, and CAHs) would report on a calendar year EHR reporting period beginning in calendar year 2017. This proposal builds on efforts to align the EHR reporting period with reporting periods for other quality reporting programs identified in the Stage 2 final rule (77 FR 53971 through 53975 and 54049 through 54051) and the FY 2015 Hospital Inpatient Prospective Payment Systems (IPPS) final rule (79 FR 49854 through 50449). In addition, all providers, other than Medicaid EPs and eligible hospitals demonstrating meaningful use for the first time, would be required to attest based on a full year of data for a single set of meaningful use objectives and measures to demonstrate Stage 3 of meaningful use, which is proposed as optional for an EHR reporting period in 2017 and mandatory for an EHR reporting period in 2018, and subsequent years for all providers participating in the Medicare and Medicaid EHR Incentive Programs.

The methodology for the selection of the proposed Stage 3 objectives and measures for the Medicare and Medicaid EHR Incentive Programs included the following:

- Review attestation data for Stages 1 and 2 of meaningful use.
- Conduct listening sessions and interviews with providers, EHR system developers, regional extension centers, and health care provider associations.
- Review recommendations from government agencies and advisory committees focused on health care improvement, such as the Health Information Technology (HIT) Policy Committee, the National Quality Forum (NQF), and the Centers for Disease Control (CDC).

The information we gathered from these sources focused on analyzing measure performance, implementing discrete EHR functionalities and standards, and examining objectives and measures presenting the best opportunity to improve patient outcomes and enhance provider support.

Based on this analysis, we are proposing a set of 8 objectives with associated measures designed to do all of the following:

- Align with national health care quality improvement efforts.
- Promote interoperability and health information exchange.
- Focus on the 3-part aim of reducing cost, improving access, and improving quality.

We intend to have this Stage 3 proposed rule be the last stage of the meaningful use framework, which leverages the structure identified in the Stage 1 and Stage 2 final rules, while simultaneously establishing a single set of objectives and measures designed to promote best practices and continued improvement in health outcomes in a sustainable manner. Measures in the Stage 1 and Stage 2 final rules that included paper-based workflows, chart abstraction, or other manual actions would be removed or transitioned to an electronic format utilizing EHR functionality for Stage 3. In addition, we are proposing the removal of ''topped out'' measures, or measures that are no longer useful in gauging performance, in order to reduce the reporting burden on providers for measures already achieving widespread adoption.

c. Clinical Quality Measurement

EPs, eligible hospitals, and CAHs must report CQMs in order to qualify for incentive payments under the Medicare and Medicaid EHR Incentive Programs and avoid downward payment adjustments under Medicare.

We are committed to continuing the electronic calculation and reporting of key clinical data through the use of CQMs. We are also focused on improving alignment of reporting requirements for CMS programs using EHR technology, maintaining flexibility with reporting requirements while streamlining reporting mechanisms for providers, and increasing quality data integrity.

This proposed rule addresses quality reporting alignment on several fronts. Our long-term vision seeks to have hospitals, clinicians, and other health care providers report through a single, aligned mechanism for multiple CMS programs. In the Stage 2 final rule, we outlined preliminary alignment options for quality reporting programs with the EHR Incentive Programs as the first step toward that vision (77 FR 54053).

In order to facilitate continuous quality improvement, we need a method to allow changes to meaningful use CQMs and the associated reporting requirements on an ongoing basis. For other CMS quality reporting programs, changes occur through the annual Medicare payment rules, such as the

Physician Fee Schedule (PFS) and the IPPS rules. Including CQMs in these annual rules would allow us to capture changes and updates annually. Therefore, we intend to further support alignment between the Medicare and Medicaid EHR Incentive Programs and other CMS quality reporting programs, such as PQRS and Hospital IQR, by including the reporting requirements for CQMs for providers demonstrating meaningful use in future rulemaking. We propose to continue encouraging CQM data submission through electronic submission for Medicare participants in 2017, and to require electronic submission of CQMs where feasible beginning in 2018 for Medicare providers demonstrating meaningful use. (We further discuss Medicaid CQM submission in section II.F.3. of this proposed rule.)

d. Payment Adjustments and Hardship Exceptions

The statute requires Medicare payment adjustment beginning in 2015. For the Stage 3 proposed rule, we propose to maintain all payment adjustment provisions for all EPs, eligible hospitals, and CAHs finalized in the Stage 2 final rule (77 FR 54093 through 54113 and 54115 through 54119) except for a change to the relationship between the EHR reporting period year and the payment adjustment year for CAHs. We are proposing a change to the timing of the EHR reporting period and related deadlines for attestations and hardship exceptions for CAHs in relation to the payment adjustment year, in order to accommodate a transition to EHR reporting for meaningful use on the calendar instead of the fiscal year timeline. The payment adjustment provisions being maintained in the Stage 3 proposed rule include the process we finalized in Stage 2 by which a prior EHR reporting period determines a payment adjustment. We also maintain the four categories of exceptions based on all of the following:

- The lack of availability of internet access or barriers to obtain IT infrastructure.
- A time-limited exception for newly practicing EPs or new hospitals that would not otherwise be able to avoid payment adjustments.
- Unforeseen circumstances such as natural disasters that would be handled on a case-by-case basis.
- (EP only) exceptions due to a combination of clinical features limiting a provider's interaction with patients or, if the EP practices at multiple locations, lack of control over the availability of CEHRT at practice locations constituting 50 percent or more of their encounters.

e. Modifications to the Medicaid EHR Incentive Program

Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for the Medicaid EHR Incentive Program. For this Stage 3 proposed rule, we propose that under the proposed changes to EHR reporting periods that would begin in 2017, Medicaid EPs and eligible hospitals demonstrating meaningful use for the first time in the Medicaid EHR Incentive Program would be required to attest for an EHR reporting period of any continuous 90-day period in the calendar year for purposes of receiving an incentive, as well as avoiding the payment adjustment under the Medicare Program.

We are proposing to continue to allow states to set up a CQM submission process that Medicaid EPs and eligible hospitals may use to report on CQMs for 2017 and subsequent years. We also propose amendments to state reporting on providers who are participating in the Medicaid EHR Incentive Program as well as state reporting on implementation and oversight activities.

f. Summary of Costs and Benefits

Upon finalization, the provisions in this proposed rule are anticipated to have an annual effect on the economy of $100 million or more, making it an economically significant rule under the Executive Order and a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the final rule. The total federal cost of the Medicare and Medicaid EHR Incentive Programs between 2017 and 2020 is estimated to be $3.7 billion in transfers. In this proposed rule we do not estimate total costs and benefits to the provider industry, but rather provide a possible per EP and per eligible hospital outlay for implementation and maintenance. Nonetheless, we believe there are substantial benefits that can be obtained by society (perhaps accruing to eligible hospitals and EPs), including cost reductions related to improvements in patient safety and patient outcomes and cost savings benefits through maximizing efficiencies in clinical and business processes facilitated by certified health IT.

TABLE 1—ESTIMATED EHR INCENTIVE PAYMENTS AND BENEFITS IMPACTS ON THE MEDICARE AND MEDICAID PROGRAMS OF THE HITECH EHR INCENTIVE PROGRAM

[Fiscal year—in billions]

Fiscal year	Medicare eligible		Medicaid eligible		Total
	Hospitals	Professionals	Hospitals	Professionals	
2017	$1.6	$0.3	$0.4	$0.8	$3.1
2018	0.0	−0.2	0.1	0.5	0.4
2019	0.0	−0.2	0.0	0.3	0.1
2020	0.0	−0.1	0.0	0.2	0.1

B. Overview of the Regulatory History

The American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5) (ARRA) amended Titles XVIII and XIX of the Act to authorize incentive payments to EPs, eligible hospitals, and CAHs, and MA organizations to promote the adoption and meaningful use of CEHRT. In the July 28, 2010 **Federal Register** (75 FR 44313 through 44588), we published a final rule (''Medicare and Medicaid Programs; Electronic Health Record Incentive Program'', or ''Stage 1 final rule'') that specified the Stage 1 criteria EPs, eligible hospitals, and CAHs must meet in order to qualify for an incentive payment, calculation of the incentive payment amounts, and other program participation requirements. For a full explanation of the amendments made by ARRA, see the Stage 1 final rule at 75 FR 44316. In that Stage 1 final rule, we also detailed that the Medicare and Medicaid EHR Incentive Program would consist of three different stages of meaningful use requirements.

In the September 4, 2012 **Federal Register** (77 FR 53967 through 54162),

we published a final rule (''Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 2; Final Rule'' or ''Stage 2 final rule'') that specified the Stage 2 criteria that EPs, eligible hospitals, and CAHs would have to meet in order to qualify for incentive payments. In addition, the Stage 2 final rule finalized payment adjustments and other program participation requirements under Medicare for covered professional and hospital services provided by EPs, eligible hospitals, and CAHs failing to demonstrate meaningful use of CEHRT, and finalized the revision of certain Stage 1 criteria, and finalized criteria that applied regardless of stage.

In the December 7, 2012 **Federal Register** (77 FR 72985), CMS and ONC jointly published an interim final rule with comment period (IFC) titled ''Health Information Technology: Revisions to the 2014 Edition Electronic Health Record Certification Criteria; and Medicare and Medicaid Programs; Revisions to the Electronic Health Record Incentive Program'' (December 7, 2012 IFC). The Department of Health and Human Services (HHS) issued the IFC to replace the Data Element Catalog (DEC) standard and the Quality Reporting Document Architecture (QRDA) Category III standard adopted in the final rule published on September 4, 2012 in the **Federal Register** with updated versions of those standards. The December 7, 2012 IFC also revised the Medicare and Medicaid EHR Incentive Programs by—

- Adding an alternative measure for the Stage 2 meaningful use (MU) objective for hospitals to provide structured electronic laboratory results to ambulatory providers;
- Correcting the regulation text for the measures associated with the objective for hospitals to provide patients the ability to view online, download, and transmit information about a hospital admission; and
- Making the case number threshold exemption for CQM reporting applicable for eligible hospitals and CAHs beginning with FY 2013.

The December 7, 2012 IFC also provided notice of our intention to issue technical corrections to the electronic specifications for CQMs released on October 25, 2012.

In the September 4, 2014 **Federal Register** (79 FR 52910 through 52933) CMS and ONC published a final rule titled ''Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program for 2014 and Other Changes to the EHR Incentive Program; and Health Information Technology: Revisions to the Certified EHR Technology Definition and EHR Certification Changes Related to Standards; Final Rule'' (''2014 CEHRT Flexibility final rule''). Due to issues related to EHR technology certified to the 2014 Edition availability delays, the 2014 CEHRT Flexibility final rule included policies allowing EPs, eligible hospitals, and CAHs that could not fully implement EHR technology certified to the 2014 Edition for an EHR reporting period in 2014 to continue to use one of the following options for reporting periods in CY 2014 and FY 2014, respectively—

- EHR technology certified to the 2011 Edition; or
- A combination of EHR technology certified to the 2011 Edition and EHR technology certified to the 2014 Edition for the EHR reporting periods.

These CEHRT options applied only to those providers that could not fully implement EHR technology certified to the 2014 Edition to meet meaningful use for an EHR reporting period in 2014 due to delays in 2014 Edition availability. Although the 2014 CEHRT flexibility final rule did not alter the attestation or hardship exception application deadlines for 2014, it did make changes to the attestation process to support these flexible options for CEHRT. This 2014 CEHRT Flexibility final rule also discussed the provisions of the December 7, 2012 IFC and finalized policies relating to the provisions contained in the December 7, 2012 IFC.

In the November 13, 2014, **Federal Register**, we published an interim final rule with comment period, under the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; Final Rule (79 FR 67976 through 67978) (November 13, 2014 IFC). Under this November 13, 2014 IFC, we recognized a hardship exception for EPs and eligible hospitals for 2014 under the established category of extreme and uncontrollable circumstances in accordance with the Secretary's discretionary authority. To accommodate this hardship exception, we further extended the hardship application deadline for EPs and eligible hospitals to November 30 for 2014 only. We also amended the regulations to allow CMS to specify a later hardship application deadline for certain hardship categories for EPs, eligible hospitals, and CAHs.

For Stages 1 and 2, CMS and ONC worked closely to ensure that the definition of meaningful use of CEHRT and the standards and certification criteria for CEHRT were coordinated. Current ONC regulations may be found at 45 CFR part 170. For this Stage 3 proposed rule, CMS and ONC will again work together to align our regulations.

We urge those interested in this Stage 3 proposed rule to also review the ONC 2015 Edition proposed rule, which is published elsewhere in this **Federal Register**. Readers may also visit: *http://www.cms.hhs.gov/EHRincentiveprograms* and *http://www.healthit.gov* for more information on the efforts at the Department of Health and Human Services (HHS) to advance HIT initiatives.

II. Provisions of the Proposed Regulations

A. Meaningful Use Requirements, Objectives, and Measures for 2017 and Subsequent Years

1. Definitions Across the Medicare Fee-for-Service, Medicare Advantage, and Medicaid Programs

a. Uniform Definitions

As discussed in both the Stage 1 and 2 final rules, we finalized several uniform definitions applicable for the Medicare FFS, Medicare Advantage, and Medicaid EHR Incentive Programs. We set forth these uniform definitions in part 495 subpart A of the regulations. We propose to maintain these definitions, unless stated otherwise in this proposed rule. (For further discussion of the uniform definitions finalized previously, we refer readers to the Stage 1 and Stage 2 final rules at 75 FR 44317 through 44321 and 77 FR 53972).

As discussed in sections II.A.1.c.(1). and (2). of this proposed rule, we are proposing a single set of criteria for meaningful use (''Stage 3'') in order to eliminate the varying stages of the EHR Incentive Programs. We propose that this Stage 3 definition of meaningful use would be optional for providers in 2017 and mandatory for all providers beginning in 2018. To support Stage 3, we propose revising the uniform definitions under 42 CFR 495.4 for ''EHR reporting period'' and ''EHR reporting period for a payment adjustment year,'' as explained later in this section. The proposed revisions to these uniform definitions include eliminating the current 90-day EHR reporting period for EPs, eligible hospitals, and CAHs demonstrating meaningful use for the first time, and instead creating a single EHR reporting period aligned to the calendar year. The proposed removal of the 90-day EHR reporting period would not apply to

Medicaid EPs and eligible hospitals demonstrating meaningful use for the first time. We believe eliminating the 90-day EHR reporting period for most providers would simplify reporting, by aligning providers on the same EHR reporting timeline across all settings. In addition, a single EHR reporting period on the calendar year would align the EHR Incentive Program with other CMS quality reporting programs using certified EHR technology such as the Hospital IQR Program and PQRS. Finally, a single EHR reporting period based on the calendar year allows for a single attestation period, thereby enabling the HHS systems to better capture data, conduct enhanced stress testing and issue resolution, and improve quality assurance of systems before each deployment. We detail the proposed revisions to each of the uniform definitions later in this section.

b. Meaningful EHR User

In the Stage 3 proposed rule, we propose to modify the definition of ''Meaningful EHR User'' under 42 CFR 495.4 to include the Stage 3 objectives and measures defined at § 495.7.

The definition of a ''Meaningful EHR User'' under the Act requires the use of certified electronic health record technology (CEHRT) (see, for example, section 1848(o)(2) of the Act). We note that the term CEHRT is a defined term for the purpose of meeting the objectives of the EHR Incentive Programs (defined at § 495.4). The term references ONC's certification criteria for a ''Base EHR,'' other ONC certification criteria required in the EHR Incentive Programs and the definition of a ''Meaningful EHR User.'' References to CEHRT within this proposed rule are to certification criteria that are required for purposes of the EHR Incentive Programs. We recognize that CEHRT is just one form of health IT. For this reason, this proposed rule also includes references to ''health IT'' where appropriate to capture the broader category of technologies where applicable.

c. Definition of Meaningful Use

(1) Considerations in Defining Meaningful Use

In sections 1848(o)(2)(A) and 1886(n)(3)(A) of the Act, the Congress identified the broad goal of expanding the use of EHRs through the concept of meaningful use. Section 1903(t)(6)(C) of the Act also requires that Medicaid providers adopt, implement, upgrade or meaningfully use CEHRT if they are to receive incentives under Title XIX. CEHRT used in a meaningful way is one piece of the broader HIT infrastructure needed to reform the health care system and improve health care quality, efficiency, and patient safety. This vision of reforming the health care system and improving health care quality, efficiency, and patient safety should inform the definition of meaningful use.

As we explained in the Stage 1 and Stage 2 rules, we seek to balance the sometimes competing considerations of health system advancement (for example, improving health care quality, encouraging widespread EHR adoption, promoting innovation) and minimizing burdens on health care providers given the short timeframe available under the HITECH Act.

Based on public and stakeholder input received during our Stage 1 rule, we laid out a phased approach to meaningful use. Such a phased approach encompasses reasonable criteria for meaningful use based on currently available technology capabilities and provider practice experience, and builds up to a more robust definition of meaningful use as technology and capabilities evolve. The HITECH Act acknowledges the need for this balance by granting the Secretary the discretion to require more stringent measures of meaningful use over time. Ultimately, consistent with other provisions of law, meaningful use of CEHRT should result in health care that is patient centered, evidence-based, prevention-oriented, efficient, and equitable.

As stated in the Stage 2 final rule (77 FR 53973), we anticipated the Stage 3 criteria for meaningful use would focus on promoting improvements in quality, efficiency, and safety leading to improved health outcomes. We also anticipated that Stage 3 would focus on clinical decision support for national high priority conditions; improving patient access to self-management tools; improving access to comprehensive patient data through robust, secure, patient-centered health information exchange; and improvements in population health.

For this Stage 3 proposed rule, we seek to streamline the criteria for meaningful use. We intend to do this by—

- Creating a single stage of meaningful use objectives and measures (Stage 3), which would be optional for all providers in 2017 and mandatory for all providers in 2018;
- Allowing providers flexible options for 2017;
- Changing the EHR reporting period to a full calendar year for all providers; and
- Aligning with other CMS quality reporting programs using certified health IT such as PQRS and Hospital IQR for clinical quality measurement.

(a) Meaningful Use Stages

Under the phased approach to meaningful use, we updated the criteria for meaningful use through staggered rulemaking, which covered Stages 1 and 2 of the EHR Incentive Program. For further explanation of the criteria we finalized under Stages 1 and 2, including the recent final rule extending Stage 2, we refer readers to 75 FR 44314 through 44588, 77 FR 53968 through 54162, and 79 FR 52910 through 52933. The current progression of the stages is outlined in Table 2.

TABLE 2—STAGE OF MEANINGFUL USE CRITERIA BY FIRST PAYMENT YEAR

First payment year	Stage of meaningful use										
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
2011	1	1	1	*1 or 2	2	2	3	3	TBD	TBD	TBD
2012	.....	1	1	*1 or 2	2	2	3	3	TBD	TBD	TBD
2013	.....	.....	1	*1	2	2	3	3	TBD	TBD	TBD
2014	.....	.....	.....	*1	1	2	2	3	3	TBD	TBD
2015	.....	.....	.....	.....	1	1	2	2	3	3	TBD
2016	.....	.....	.....	.....	.....	1	1	2	2	3	3
2017	.....	.....	.....	.....	.....	.....	1	1	2	2	3

*3-month quarter EHR reporting period for Medicare and continuous 90-day EHR reporting period (or 3 months at Stage option) for Medicaid EPs. All providers in the first year in 2014 use any continuous 90-day EHR reporting period.

In the Stage 2 final rule (77 FR 53974), we also stated that we would indicate in future rulemaking our intent for the potential development of stages or further criteria beyond Stage 3. In this proposed rule, we intend for Stage 3 to be the final stage in meaningful use and that no further stages would be developed. However, we understand that multiple technological and clinical care standard changes associated with EHR technology may result in the need to consider changes to the objectives and measures of meaningful use under the EHR Incentive Programs. Accordingly, we note that, as circumstances warrant, we would consider addressing such changes in future rulemaking.

As shown in Table 2, providers in any given year may be participating in 1 of 3 different stages of the EHR Incentive Programs in addition to other CMS quality reporting programs using certified health IT such as PQRS and Hospital IQR. Through listening sessions, correspondence, and public comment forums, providers expressed frustration regarding the competing reporting requirements of multiple CMS programs, and the overall challenge of planning and reporting on the complex and numerous meaningful use requirements, including the need to manage changing processes, workflows, and reporting systems. In addition, group practices with EPs in different stages of meaningful use have to simultaneously support multiple stages of the program in order to demonstrate meaningful use for each EP. Meanwhile, if the current 3-stage framework continues, HHS and state systems would be required to support all 3 stages of the EHR Incentive Programs in perpetuity with extensive implementation of complex processes to accept submissions, analyze data, and coordinate systems.

Providers have expressed ongoing concern that the EHR Incentive Programs are complicated, not focused on clinical reality and workflow, and stifling to innovation in health IT development. Specifically, providers have expressed concerns about the number of Stage 1 and 2 objectives and measures becoming obsolete or lacking any link to improving outcomes. In addition, providers have expressed concern that continued focus on Stage 1 measures impedes current and potential future innovation in advanced utilization of health information technology. Providers worry that Stage 3 of meaningful use would exacerbate these existing concerns.

The certified EHR technology requirements within the EHR Incentive Programs and included in ONC's Health IT Certification Program have resulted in considerable increases in certified EHR technology adoption among providers and are paving the way for more comprehensive, patient-centered care across the care continuum. We recognize that while these advancements have been beneficial there are concerns, as stated previously, that require careful examination to ensure the sustainability and efficacy of the program going forward—as HHS moves to further encourage new uses of health IT and support the developing health IT infrastructure beyond the strides already made. Therefore, we seek to set a new foundation for this evolving program by proposing a number of changes to meaningful use. First, we propose a definition of meaningful use that would apply beginning in 2017. This definition of meaningful use, although referred to as ''Stage 3'', would be the only definition for the Medicare and Medicaid EHR Incentive Programs, and would incorporate certain requirements and aspects of Stages 1 and 2. Beginning with 2018, we propose to require all EPs, eligible hospitals, and CAHs, regardless of their prior participation in the EHR Incentive Program, to satisfy the requirements, objectives, and measures of Stage 3. However, for 2017, we propose that Stage 3 would be optional for providers. This option would allow for a provider to move on to Stage 3 in 2017 or remain at Stage 2, or for some providers to remain at Stage 1, depending on their participation timeline. For example, under this proposal, a provider in Stage 2 in 2016 could choose to remain in Stage 2 in 2017 or progress to Stage 3. In contrast to our rulemaking in 2014 to accommodate the use of multiple Editions to meet the definitions of CEHRT during the EHR reporting periods in that year, this policy is based on the provider selection of the objectives and measures for their demonstration of meaningful use in 2017. Both the EHR technology certified to the 2014 Edition and the EHR technology certified to the 2015 Edition will support attestations for Stage 1 or Stage 2 in 2017. In addition, the development and certification process for EHR technology products is not dependent on this selection by individual providers. Therefore, we do not expect that this policy would affect the availability of EHR technology certified to the 2015 Edition in 2017 or the ability of an individual provider to implement EHR technology certified to the 2015 Edition during the year regardless of which stage they choose for their EHR reporting period in 2017. Therefore, we are proposing in section II.A.2.b. that all providers would be required to use EHR technology certified to the 2015 Edition for a full calendar year for the EHR reporting period in 2018. The revised timeline based on these proposals is outlined in Table 3.

TABLE 3—STAGE OF MEANINGFUL USE CRITERIA BY FIRST YEAR

First year as a meaningful EHR user	Stage of meaningful use										
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021 and future years
2011	1	1	1	*2	2	2	2 or 3	3	3	3	3
2012	.....	1	1	*2	2	2	2 or 3	3	3	3	3
2013	.....	.....	1	1	2	2	2 or 3	3	3	3	3
2014	.....	.....	.....	1	1	2	2 or 3	3	3	3	3
2015	.....	.....	.....	.....	1	1	1, 2 or 3	3	3	3	3
2016	.....	.....	.....	.....	.....	1	1, 2 or 3	3	3	3	3
2017	.....	.....	.....	.....	.....	.....	1, 2 or 3	3	3	3	3
2018 and future years	.....	.....	.....	.....	.....	.....	.....	3	3	3	3

* Please note, a provider scheduled to participate in Stage 2 in 2014, who instead elected to demonstrate stage 1 because of delays in availability of EHR technology certified to the 2014 Edition, is still considered a stage 2 provider in 2014 despite the alternate demonstration of meaningful use. In 2015, all such providers are considered to be participating in their second year of Stage 2 of meaningful use.

Please note that the Medicare EHR Incentive Program and the Medicaid EHR Incentive Program have different rules regarding the number of payment years available, the last year for which incentive payments may be received, and the last year to initiate the program and receive an incentive payment. Medicaid EPs and eligible hospitals can receive a Medicaid EHR incentive payment for ''adopting, implementing, and upgrading'' (AIU) to Certified EHR Technology for their first payment year, which is not reflected in Table 3. The applicable payment years and the incentive payments available for each program are discussed in the Stage 1 final rule (75 FR 44318 through 44320). Although Table 3 outlines a provider's progression through the stages of meaningful use, it does not necessarily reflect the relation to incentive payments in the Medicare or Medicaid EHR Incentive Programs. We note that some providers may not ever qualify to receive an incentive payment depending on, among other factors, when and whether they successfully demonstrate meaningful use in the EHR Incentive Programs. We intend for the timeline in Table 3 to also apply to those EPs, eligible hospitals, and CAHs that never receive an incentive payment under the EHR Incentive Programs.

We are further proposing that Stage 3 would adopt a simplified reporting structure on a focused set of objectives and associated measures to replace all criteria under Stages 1 and 2. Specifically, we are proposing criteria for meaningful use for EPs, eligible hospitals, and CAHs (optional in 2017 and mandatory beginning in 2018), regardless of a provider's prior participation in the Medicare and Medicaid EHR Incentive Programs, as described in detail in section II.A.1.c. of this proposed rule. We believe that a single set of objectives would reduce provider burden and allow for greater focus on improving outcomes, enhancing interoperability, and increasing patient engagement. In addition, with all providers participating at the same level, the impact of the scale of participation helps to support growth in health information exchange and patient engagement infrastructure, as more providers participate the ease of participation increases. Finally, the associated measures proposed for Stage 3 in this proposed rule would use advanced EHR functionality and IT-based processes. The requirements, objectives, and measures are outlined further in sections II.A.1.c.(2). of this proposed rule. In order to maintain clarity in relation to the various rules and stages, provisions outlined in the Stage 1 or Stage 2 final rules, and proposals under this Stage 3 proposed rule, we will maintain the ''Stage'' designation in order to indicate the rule that contains the provision. The requirements, objectives, and measures proposed as part of this proposed definition of meaningful use would be referred to as ''Stage 3''.

We welcome public comment on these proposals.

(b) EHR Reporting Period

In the Stage 1 and Stage 2 final rules, we established that the EHR reporting period for eligible hospitals and CAHs is based on the federal fiscal year (October 1 through September 30). This fiscal year EHR reporting period originally was designed to support coordination between program implementation and CMS payment systems following the development of the EHR Incentive Programs in 2010 to allow for efficient payment of incentives for eligible hospitals and CAHs. However, as the EHR Incentive Program evolved, we found the fiscal year EHR reporting period resulted in varying reporting timelines between provider types (for example, the EHR reporting period for EPs is based on the calendar year) and a shortened timeline for system developers to meet hospital and CAH technology requirements. Enhanced coordination between CMS programs and other system implementation changes have subsequently made it unnecessary to maintain a reporting timeframe for eligible hospitals and CAHs based on the federal fiscal year. Therefore, we are proposing changes to the EHR reporting period beginning with the EHR reporting period in 2017 in order to do all of the following:

- Simplify reporting for providers, especially groups and diverse systems.
- Support further alignment of CMS quality reporting programs using certified health IT such as Hospital IQR and PQRS.
- Simplify HHS system requirements for data capture.
- Provide for greater flexibility, stress testing, and Quality Assurance (QA) of systems before deployment.

In the FY 2015 IPPS final rule (79 FR 49853 through 50449), we aligned the reporting and submission timelines for CQMs for the Medicare EHR Incentive Programs for eligible hospitals and CAHs with the reporting and submission timelines for the Hospital IQR Program on a calendar year basis. This was designed to allow for better alignment between these programs in light of the directive in section 1886(n)(3)(B)(iii) of the Act to avoid redundant or duplicative reporting. Calendar year reporting on quality data for hospitals allows for greater efficiency in measure development, the electronic specification of measures, and the update and deployment of measure logic and value sets for electronic clinical quality measures. The FY 2014 IPPS final rule (78 FR 50904) clarified that eligible hospitals and CAHs demonstrating meaningful use for the first time in FY 2014 and reporting on CQMs electronically must report on a 3-month quarter in FY 2014, rather than on a continuous 90-day period. Such changes not only better align program reporting but also allow for better data integrity as previously discussed in the Stage 2 final rule (77 FR 53974 through 53975) and further discussed in section II.B.1.b. of this proposed rule.

(i) Calendar Year Reporting

We are proposing to change the definitions of ''EHR reporting period'' and ''EHR reporting period for a payment adjustment year'' under § 495.4 for EPs, eligible hospitals, and CAHs such that the EHR reporting period would be one full calendar year, with a limited exception under the Medicaid EHR Incentive Program for providers demonstrating meaningful use for the first time as discussed later in this section and in section II.A.2.b. of this proposed rule. This would allow for the full alignment of the EHR reporting timeline for the meaningful use objectives and associated measures and the CQMs, and align the timing of reporting by EPs, eligible hospitals, and CAHs. We propose this change would apply beginning in CY 2017. For example, for the incentive payments for the 2017 payment year, the EHR reporting period for EPs, eligible hospitals, and CAHs would be the full 2017 calendar year. We note that the incentive payments under Medicare FFS and Medicare Advantage (MA) (sections 1848(o), 1886(n), 1814(l)(3), 1853(l) and (m) of the Act) will end before 2017. However, under this proposed change, EPs and eligible hospitals that seek to qualify for an incentive payment under Medicaid would have a full calendar year EHR reporting period if they are not demonstrating meaningful use for the first time. For the payment adjustments under Medicare, we discuss the timing of the EHR reporting period in relation to the payment adjustment year in section II.D.2. of this proposed rule.

This proposal would mean that eligible hospitals and CAHs would have

a reporting gap for the objectives and measures of meaningful use consisting of the 3-month quarter from October 1, 2016 through December 31, 2016. Depending on future rulemaking, eligible hospitals and CAHs may still be required to report on CQMs over this time. The next EHR reporting period for eligible hospitals and CAHs to collect data on the objectives and measures of meaningful use would then begin on January 1, 2017 and end on December 31, 2017. Eligible hospitals and CAHs would then report on a full calendar year basis from that point forward.

(ii) Eliminate 90-Day EHR Reporting Period

We are further proposing to eliminate the 90-day EHR reporting period for new meaningful EHR users beginning in 2017, with a limited exception for Medicaid EPs and eligible hospitals demonstrating meaningful use for the first time. This would allow for a single EHR reporting period of a full calendar year for all providers across all settings. Specifically, we propose to eliminate the EHR reporting period of any continuous 90 days for EPs, eligible hospitals, and CAHs that are demonstrating meaningful use for the first time. Those providers instead would have an EHR reporting period of a full calendar year, as described previously. However, as discussed in section II.A.2.b. of this proposed rule, we propose to maintain the 90-day EHR reporting period for a provider's first payment year based on meaningful use for EPs and eligible hospitals participating in the Medicaid EHR Incentive Program. We propose corresponding revisions to the definitions of ''EHR reporting period'' and ''EHR reporting period for a payment adjustment year'' under § 495.4. We propose these changes would apply beginning in CY 2017.

As stated previously, all providers would attest based on a single EHR reporting period consisting of one full calendar year for the applicable objectives and measures of meaningful use in 2017 and subsequent years. These providers would submit their data in the 2 months following the close of the EHR reporting period. For further information on the submission methods, see section II.D.9.b. of this proposed rule.

We welcome public comment on these proposals.

(iii) State Flexibility for Stage 3 of Meaningful Use

Consistent with our approach under both Stage 1 and 2, we propose to continue to offer states flexibility under the Medicaid EHR Incentive Program in Stage 3 by adding a new provision at § 495.316(d)(2)(iii) subject to the same conditions and standards as the Stage 2 flexibility policy. Under Stage 3, state flexibility would apply only with respect to the public health and clinical data registry reporting objective outlined under section II.A.1.c.(1).(b).(i). of this proposed rule.

For Stage 3 of meaningful use, we would continue to allow states to specify the means of transmission of the data and otherwise change the public health agency reporting objective as long as it does not require functionality greater than what is required for Stage 3 and included in the 2015 Edition proposed rule elsewhere in this issue of the **Federal Register**.

We welcome comment on this proposal.

(2) Criteria for Meaningful Use Stage 3

In the Stage 1 and Stage 2 final rules, meaningful use included the concept of a core and a menu set of objectives. Each objective had associated measures that a provider needed to meet as part of demonstrating meaningful use of CEHRT. In Stage 2 of meaningful use, we also combined some of the objectives of Stage 1 and incorporated them into objectives for Stage 2. For example, we combined the objectives of maintaining an up-to-date problem list, active medication list, and active medication allergy list with the objective of providing a summary of care record for each transition of care or referral through required fields in the summary of care document (77 FR 53990 through 53991 and 77 FR 54013 through 54016). We did this to allow for the more advanced use of EHR technology functions to support clinical processes, and to eliminate the need for providers to individually report on measures that were often already incorporated in workflows and for which many providers were already meeting the threshold (known as ''topping out''). In the Stage 2 final rule (77 FR 53973), we signaled that the Stage 2 core and menu objectives would all be included in the Stage 3 proposal for meaningful use.

Since the publication of the Stage 2 final rule, we have reviewed meaningful use performance from both a qualitative and quantitative perspective including analyzing performance rates, reviewing CEHRT functionalities and standards, and considering information gained by engaging with providers through listening sessions, correspondence, and open forums like the HIT Policy Committee. The data support a number of key points for consideration:

- Providers are performing higher than the thresholds for some of the meaningful use measures using some EHR functionalities that—prior to the Stage 1 and Stage 2 final rules—were not common place (such as the maintenance of problem lists).
- Providers in different specialties and settings implemented CEHRT and met objectives in different ways.
- Providers express support for reducing the reporting burden on measures that have ''topped out.''
- Providers expressed support for advanced functionality that would offer value to providers and patients.
- Providers expressed support for flexibility regarding how objectives are implemented in their practice settings.
- Providers in health systems and large group practices expressed frustration about the reporting burden of having to compile multiple reports spanning multiple stages and objectives.

Since the EHR Incentive Programs began in 2011, stakeholder associations and providers have requested that we consider changes to the number of objectives and measures that providers must meet to demonstrate meaningful use of certified EHR technology under the EHR Incentive Programs. These recommendations also extended to considerations for the structure of Stage 3 of meaningful use. Many of these recommendations include allowing a provider to fail any two objectives (in effect making all objectives ''menu'' objectives) and still meet meaningful use, or to allow providers to receive an incentive payment or avoid a downward payment adjustment based on varied percentages of performance, and removing all measure thresholds. We have reviewed these recommendations and have declined to follow this course for a number of reasons.

First, the statute specifically requires the Secretary to seek to improve the use of EHR and health care quality over time by requiring more stringent measures of meaningful use (see, for example, section 1848(o)(2)(A)(iii) of the Act). This is one reason why we established stages of meaningful use to move providers along a progression from adoption to advanced use of certified EHR technology. Therefore, we intend to continue to use measure thresholds that may increase over time, and to incorporate advanced use functions of certified EHR technology into meaningful use objectives and measures.

Second, there are certain objectives and measures which capture policies specifically required by the statute as core goals of meaningful use of certified EHR technology, such as electronic

prescribing for EPs, health information exchange, and clinical quality measurement (see sections 1848(o)(2)(A) and 1886(n)(3)(A) of the Act). Specific to the health information exchange, the statute requires certified EHR technology connected in a manner that provides for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination.

Further, the statute requires that the certified EHR technology which providers must use shall be a ''qualified EHR'' as defined in section 3000(13) of the Public Health Service Act as an electronic record of health-related information on an individual that includes patient demographic and clinical health information, such as medical history and problem lists; and has the capacity to—

- Provide clinical decision support;
- Support physician order entry;
- Capture and query information relevant to health care quality; and
- Exchange electronic health information with, and integrate such information from, other sources (see section 1848(o)(4) of the Act).

The objectives that address these requirements are integral to the foundational goals of the program, which would be undermined if providers were allowed to fail to meet these objectives and still be considered meaningful EHR users. For these reasons, we intend to continue to require providers to meet the objectives and measures of meaningful use as required for the program, rather than allowing providers to fail any two objectives of their choice or making all objectives menu objectives.

Finally, while we understand providers are seeking to reduce the overall burden of reporting, we do not believe these recommendations accomplish that goal. Adding all objectives and measures to the menu set and allowing for varying degrees of participation may add complexity for the individual provider seeking to determine how they can meet the requirements and demonstrate meaningful use of certified EHR technology. We instead are proposing (as discussed in sections II.A.1. and II.B. of this proposed rule) to reduce provider burden and simplify the program by aligning reporting periods and CQM reporting. In addition, the statute provides that in selecting measures for the EHR Incentive Program, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required, including reporting under the PQRS and Hospital IQR Program (see sections 1848(o)(2)(B)(iii) and 1886(n)(3)(B)(iii) of the Act). Although the statute refers to redundant or duplicative reporting in the context of other CMS quality reporting programs, we believe it is also useful and appropriate to consider whether there are redundant or duplicative aspects of the objectives and measures of Stages 1 and 2 of meaningful use as we develop policies for Stage 3.

To that end, we have analyzed the objectives and measures of meaningful use in Stage 1 and Stage 2 of the program to determine where measures are redundant, duplicative, or have ''topped out.'' ''Topped out'' is the term used to describe measures that have achieved widespread adoption at a high rate of performance and no longer represent a basis upon which provider performance may be differentiated. We considered redundant objectives and measures to include those where a viable health IT-based solution may replace paper-based actions, such as the Stage 2 Clinical Summary objective (77 FR 54001 and 54002). We considered duplicative objectives and measures to include those where some aspect is also captured in the course of meeting another objective or measure, such as recording vital signs which is also required as part of the summary of care document under the Stage 2 Summary of Care objective (77 FR 54013 through 54021). Finally, measures which have ''topped out'' do not provide a meaningful gain in the effort to improve the use of EHR and health care quality over time by requiring more stringent measures of meaningful use as directed in the statute (see section 1848(o)(2)(A)(iii) of the Act). For further discussion of ''topped out'' measures, we direct readers to section II.A.2.a. of this proposed rule.

Therefore, our proposals for Stage 3 would continue the precedent of focusing on the advanced use of certified EHR technology. They would reduce the reporting burden; eliminate measures that are now redundant, duplicative, and ''topped out''; create a single set of objectives for all providers with limited variation between EPs, eligible hospitals, and CAHs as necessary; and provide flexibility within the objectives to allow providers to focus on implementations that support their practice.

(a) Topped Out Objectives and Measures

In other contexts and CMS programs, CQMs are regularly evaluated to determine whether they have ''topped out,'' which means generally that measure performance among providers is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. Examples of this type of evaluation are found in the Hospital Inpatient Quality Reporting (IQR) program, the Hospital-Value Based Purchasing (HVBP) program, the End-Stage Renal Disease (ESRD) Quality Initiative, and within the National Quality Forum (NQF) endorsement and maintenance process for CQMs. We believe that quality measures, once ''topped-out,'' represent care standards that have been widely adopted. We believe such measures should be considered for removal from program reporting because their associated reporting burden may outweigh the value of the quality information they provide and because, in some cases, the inclusion of these measures may impact the ability to differentiate among provider performance as a whole for programs which use baseline and benchmarking based on measure performance scores. Therefore, measures are regularly subject to an evaluation process to identify their continued efficacy. This evaluation process is used to determine whether a measure is ''topped out'' and, if so, whether that measure should be removed from program reporting requirements. We note that both the identification and the determination of a measure are part of the process as a measure may be identified as topped out, but still be determined useful as a measure for a specific program because of other factors that merit continued use of the measure.

While the EHR Incentive Program does not use a benchmarking system to rate the overall and relative performance of providers as part of the definitions of meaningful use; we are proposing to adopt an approach to evaluate whether objectives and measures have become ''topped out'' and, if so, whether a particular objective or measure should be considered for removal from reporting requirements. We propose to apply the following two criteria, which are similar to the criteria used in the Hospital IQR and HVBP Programs (79 FR 50203): 1—Statistically indistinguishable performance at the 75th and 99th percentile, and 2—performance distribution curves at the 25th, 50th, and 75th percentiles as compared to the required measure threshold.

An example of a current Stage 1 objective which would be considered ''topped out'' under this approach is the objective to record demographics (75 FR 44340 through 44343). For the record demographics objective, we reviewed performance data submitted by providers through attestation and

determined that across all years of participation, the 75th percentile is performing at 99.8 percent with the 99th percentile performing at 100 percent. In addition, the 25th, 50th, and 75th percentiles are all performing with minimal variance and significantly higher than the measure threshold of 50 percent, with performance rates at 97 percent, 99 percent, and 100 percent respectively for eligible hospitals and 92 percent, 98 percent and 100 percent respectively for EPs in Stage 1.[1] For more information on the performance data, please see the EHR Incentive Programs Objective and Measure Performance Report by Percentile available at *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html.* We further note that this particular objective may also be considered duplicative as further discussed in section II.A.2.c. of this proposed rule, as the functionality which supports the objective within the EHR is also used in other objectives such as the objective to provide patient-specific education resources (77 FR 54011 through 54012) and the Stage 2 summary of care objective (77 FR 54013 through 54021). Therefore, this is an example of an objective that we determined is topped out and may no longer provide value as an independent objective in the program.

We welcome public comments on our proposed approach for topped out objectives and measures.

(b) Electronic Versus Paper-Based Objectives and Measures

In Stages 1 and 2, we require or allow providers the option to include paper-based formats for certain objectives and measures. For these objectives and measures, providers would print, fax, mail, or otherwise produce a paper document and manually count these actions to include in the measure calculation. Examples of these include: The provision of a non-electronic summary of care document for a transition or referral to meet the measure at § 495.6(j)(14)(i) for EPs and for eligible hospitals and CAHs at§ 495.6(l)(11)(i): ''The [provider] who transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals;'' and the provision of paper-based patient education materials measure for at § 495.6(j)(12)(i) for EPs and § 495.6(l)(9)(i) requiring: ''Patient-specific education resources identified by Certified EHR Technology are provided to patients for more than 10 percent of all unique patients with office visits seen by the EP [or discharged from the eligible hospital or CAH] during the EHR reporting period.'' Each of these measures may be met using a non-electronic format or action, and we propose to discontinue this policy for Stage 3. We recognize the strides that providers have made in the use of CEHRT and as we move forward in MU, it is appropriate to remove the earlier iterations of objectives and measures that were designed to support beginning EHR use and instead focus on objectives that are based solely on electronic use of data. This does not imply that we do not support the continued use of paper-based materials in a practice setting. Some patients may prefer to receive a paper version of their clinical summary or may want to receive education items or reminders on paper or some other method that is not electronic. We strongly recommend that providers continue to provide patients with visit summaries, patient health information, and preventative care recommendations in the format that is most relevant for each individual patient and easiest for that patient to access. In some cases, this may include the continued use of non-IT-based resources. We are simply proposing that paper-based formats would not be required or allowed for the purposes of the objectives and measures for Stage 3 of meaningful use. We welcome public comments on this proposal.

(c) Advanced EHR Functions

As discussed in section II.A.1.c.(2).(a). of this proposed rule, we are proposing to simplify requirements for meaningful use through an analysis of existing objectives and measures for Stages 1 and 2 to determine if they are redundant, duplicative, or ''topped out''. We note that some of the objectives and measures which meet these criteria involve EHR functions that are required by the statutory definition of ''certified EHR technology'' (see section 1848(o)(4) of the Act, which references the definition of ''qualified EHR'' in section 3000(13) of the Public Health Service Act) which a provider must use to demonstrate meaningful use. The objectives and measures proposed for Stage 3 would include uses of these functions in a more advanced form. For example, patient demographic information is included in an electronic summary of care document called a consolidated clinical document architecture (CCDA) provided during a transition of care in the Stage 2 Summary of Care objective and measures (77 FR 54013 through 54021), which represents a more advanced use of the EHR function than in the Stage 1 and 2 objective to record patient demographic information (77 FR 53991 through 53993).

We adopted a multi-part approach to identify the objectives and measures which would be proposed for providers to demonstrate meaningful use for Stage 3. This methodology included the analysis mentioned previously of existing Stage 1 and 2 objectives and measures, and provider performance; a review and consideration of the HIT Policy Committee recommendations (which are publically available for review at: *http://www.healthit.gov/facas/health-it-policy-committee/health-it-policy-committee-recommendations-national-coordinator-health-it*); and an evaluation of how the potential objectives and measures align with the foundational goals of the program defined in the HITECH Act.

In the Stage 2 proposed and final rules, we often identified the HIT Policy Committee recommendations as part of our discussion of the specific objectives and measures, for example in the Stage 2 CPOE objective at 77 FR 43985. In this proposed rule for Stage 3 of meaningful use, although we have considered the HIT Policy Committee's recommendations in developing our proposed policies, we are not referencing the recommendations in each individual proposed objective and measure as there are multiple factors that contribute to the selection of each proposed objective and measure. In addition, many of the HIT Policy Committee recommendations address functions and standards that are part of the advanced use of certified EHR technology captured by one or more objectives proposed for Stage 3 of meaningful use. For example, the HIT Policy Committee has recommended an expansion of demographic data captured as structured data as well as a change to the related standards for use. However, this function and standard is required for certification of EHR technology for meaningful use and it is a required field for an electronic summary of care document for health information exchange. It is also to be included in the information accessible to a patient within their electronic patient record. Therefore, to provide clarity for readers, we provide a notation within Table 4 to identify alignment between the proposed Stage 3 objectives and measures and the recommendations of the HIT Policy Committee for Stage 3 of meaningful

[1] Data may be found on the CMS Web site data and program reports page: *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html.*

use. We direct readers to the HIT Policy Committee recommendations available on HealthIT.gov for further information (*http://www.healthit.gov/facas/health-it-policy-committee/health-it-policy-committee-recommendations-national-coordinator-health-it*).

As mentioned previously, the statute includes certain foundational goals and requirements for meaningful use of certified EHR technology and the functions of that technology. Therefore, after review of the existing Stage 1 and Stage 2 objectives and measures of meaningful use, the recommendations of the HIT Policy Committee, and the foundational goals and requirements under the HITECH Act; we have identified eight key policy areas which represent the advanced use of EHR technology and align with the program's foundational goals and overall national health care improvement goals, such as those found in the CMS National Quality Strategy.[2] These eight policy areas provide the basis for the proposed objectives and measures for Stage 3 of meaningful use. They are included in Table 4 as follows:

TABLE 4—OBJECTIVES AND MEASURES FOR MEANINGFUL USE IN 2017 AND SUBSEQUENT YEARS

Program goal/objective	Delivery system reform goal alignment
Protect Patient Health Information	Foundational to Meaningful Use and Certified EHR Technology*. Recommended by HIT Policy Committee.
Electronic Prescribing (eRx)	Foundational to Meaningful Use. National Quality Strategy Alignment.
Clinical Decision Support (CDS)	Foundational to Certified EHR Technology. Recommended by HIT Policy Committee. National Quality Strategy Alignment.
Computerized Provider Order Entry (CPOE)	Foundational to Certified EHR Technology. National Quality Strategy Alignment.
Patient Electronic Access to Health Information	Recommended by HIT Policy Committee. National Quality Strategy Alignment.
Coordination of Care through Patient Engagement	Recommended by HIT Policy Committee. National Quality Strategy Alignment.
Health Information Exchange (HIE)	Foundational to Meaningful Use and Certified EHR Technology. Recommended by HIT Policy Committee. National Quality Strategy Alignment.
Public Health and Clinical Data Registry Reporting	Recommended by HIT Policy Committee. National Quality Strategy Alignment.

* See, for example, sections 1848(o)(2) and (4) of the Act.

These objectives build on the measures and EHR functionalities from the Stage 1 final rule and the Stage 2 final rule to advance the core functions of EHRs in a clinically relevant way that benefits providers and patients.

Under this proposal, which would apply to Stage 3 of meaningful use in 2017 and subsequent years, providers must successfully attest to these eight objectives and the associated measures (or meet the exclusion criteria for the applicable measure). As mentioned previously, the statute requires the Secretary to seek to improve the use of EHR and health care quality over time by requiring more stringent measures of meaningful use (see section 1848(o)(2)(A)(iii) of the Act). While we are proposing to simplify the program by removing topped-out, redundant, and duplicative measures and aligning reporting periods for providers; we are maintaining the push to improve the use of EHRs over time through these eight objectives and the associated measures proposed for Stage 3 of meaningful use. These proposed objectives and measures include advanced EHR functions, use a wide range of structured standards in CEHRT, employ increased thresholds over similar Stage 1 and 2 measures, support more complex clinical and care coordination processes, and require enhanced care coordination through patient engagement through a flexibility structure of active engagement measures.

These proposed objectives and their associated measures are further discussed in section II.A.1.(c).(2). of this proposed rule. CMS and ONC will continue to monitor and review performance on the objectives and measures finalized for Stage 3 to continue to evaluate them for rigor and efficacy and, if necessary, propose changes in future rulemaking.

(d) Flexibility Within Meaningful Use Objectives and Measures

We are proposing to incorporate flexibility within certain objectives proposed for Stage 3 for providers to choose the measures most relevant to their unique practice setting. This means that as part of successfully demonstrating meaningful use, providers would be required to attest to the results for the numerators and denominators of all measures associated with an objective; however, a provider would only need to meet the thresholds for two of the three associated measures. The proposed Stage 3 objectives including flexible measure options are as follows:

- Coordination of Care through Patient Engagement—Providers must meet the thresholds of two of three measures and must attest to the numerators and denominators of all three measures.
- Health Information Exchange—Providers must meet the thresholds of two of three measures and must attest to the numerators and denominators of all three measures.
- Public Health Reporting—EPs must report on three measures and eligible hospitals and CAHs must report on four measures.

We propose that if a provider meets the exclusion criteria for a particular measure within an objective which allows providers to meet the thresholds for two of three measures (namely, the Coordination of Care through Patient Engagement objective and the Health Information Exchange objective), the provider may exclude the measure and must meet the thresholds of the remaining two measures to meet the

[2] The National Quality Strategy: ''HHS National Strategy for Quality Improvement in Health Care'' *http://www.ahrq.gov/workingforquality/about.htm.*

objective. If a provider meets the exclusion criteria for two measures for such an objective, the provider may exclude those measures and must meet the threshold of the remaining measure to meet the objective. If a provider meets the exclusion criteria for all three measures for such an objective, the provider may exclude those measures and would be considered to have met the objective.

We discuss the proposed policy for exclusions for the public health reporting objective as well as the exclusion criteria in further detail within the individual objectives and measures in section II.A.1.(c).(2). of this proposed rule.

(e) EPs Practicing in Multiple Practices/Locations

For Stage 3, we propose to maintain the policy from the Stage 2 final rule (77 FR 53981) which states that to be a meaningful user, an EP must have 50 percent or more of his or her outpatient encounters during the EHR reporting period at a practice/location or practices/locations equipped with CEHRT. An EP who does not conduct at least 50 percent of their patient encounters in any one practice/location would have to meet the 50 percent threshold through a combination of practices/locations equipped with CEHRT. For example, if the EP practices at a federally qualified health center (FQHC) and within his or her individual practice at two different locations, we would include in our review all three of these locations, and CEHRT would have to be available at one location or a combination of locations where the EP has 50 percent or more of his or her patient encounters. If CEHRT is only available at one location, then only encounters at this location would be included in meaningful use assuming this one location represents 50 percent or more of the EP's patient encounters. If CEHRT is available at multiple locations that collectively represent 50 percent or more of the EP's patient encounters, then all encounters from those locations would be included in meaningful use. In the Stage 2 final rule at (77 FR 53981), we defined patient encounter as any encounter where a medical treatment is provided or evaluation and management services are provided. This includes both individually billed events and events that are globally billed, but are separate encounters under our definition.

In addition, in the Stage 2 final rule at (77 FR 53981) we defined a practice/location as equipped with CEHRT if the record of the patient encounter that occurs at that practice/location is created and maintained in CEHRT. This can be accomplished in the following three ways: CEHRT could be permanently installed at the practice/location, the EP could bring CEHRT to the practice/location on a portable computing device, or the EP could access CEHRT remotely using computing devices at the practice/location. We propose to maintain these definitions for Stage 3.

(f) Denominators

The objectives for Stage 3 of meaningful use include percentage-based measures wherever possible. In the Stage 2 final rule, we included a discussion of the denominators used for the program that included the use of one of four denominators for each of the measures associated with the meaningful use objectives outlined in the Stage 2 final rule at 77 FR 53982 for EPs and 77 FR 53983 for eligible hospitals and CAHs. We focused on denominators because the action that moves something from the denominator to the numerator requires the use of CEHRT by the provider. For Stage 3 we refer readers to each of the proposed objectives and measures for Stage 3 for the specific calculation of each denominator for each measure. Here, we simply outline the general proposals for determining the scope of the measure denominators.

For EPs, the references used to define the scope of the potential denominators for measures include the following:

- Unique patients seen by the EP during the EHR reporting period. The scope for this calculation may be limited to only those patients whose records are maintained in the EHR for the denominator of the measures for objectives other than those referencing ''unique patients'' as previously established in the Stage 2 final rule at (77 FR 53981). We propose to maintain the policy that EPs who practice at multiple locations or switch CEHRT during the EHR reporting period may determine for themselves the method for counting unique patients in the denominators to count unique patient across all locations equipped with different CEHRT, or to count at each location equipped with CEHRT. In cases where a provider switches CEHRT products at a single location during the EHR reporting period, they also have the flexibility to count a patient as unique on each side of the switch and not across it. EPs in these scenarios must choose one of these methods for counting unique patients and apply it consistently throughout the entire EHR reporting period.

A patient is seen by the EP when the EP has a real time physical encounter with the patient in which they render any service to the patient. We also consider a patient seen through telehealth as a patient ''seen by the EP'' (telehealth may include the commonly known telemedicine as well as telepsychiatry, telenursing, and other diverse forms of technology-assisted health care). However, in cases where the EP and the patient do not have a real time physical or telehealth encounter, but the EP renders a consultative service for the patient, such as reading an EKG, virtual visits, or asynchronous telehealth, the EP may choose whether to include the patient in the denominator as ''seen by the EP.'' This is necessary so that these providers can avoid reporting a zero in the denominator and be able to satisfy meaningful use. However, we stress that once providers choose, they must maintain that denominator choice for the entire EHR reporting period and for all relevant meaningful use measures.

- Office visits. The denominators of the measures that reference ''office visits'' may be limited to only those patients whose records are maintained using CEHRT. An office visit is defined as any billable visit that includes the following:

++ Concurrent care or transfer of care visits,

++ Consultant visits, or

++ Prolonged physician service without direct, face-to-face patient contact (for example, telehealth).

- All medication, laboratory, and diagnostic imaging orders created during the reporting period
- Transitions of care and referrals including at least—

++ When the EP is the recipient of the transition or referral, the first encounter with a new patient and encounters with existing patients where a summary of care record (of any type) is provided to the receiving EP; and

++ When the EP is the initiator of the transition or referral, transitions and referrals ordered by the EP.

Transitions of care are the movement of a patient from one setting of care to another. Referrals are cases where one provider refers a patient to another, but the referring provider maintains their care of the patient as well. For the purposes of distinguishing settings of care in determining the movement of a patient, we propose that a transition or referral may take place when a patient is transitioned or referred between providers with different billing identities, such as a different National Provider Identifier (NPI) or hospital CMS Certification Number (CCN). We

also propose that in the cases where a provider has a patient who seeks out and receives care from another provider without a prior referral, the first provider may include that transition as a referral if the patient subsequently identifies the other provider of care.

For further explanation of the terms ''unique patient,'' ''seen by the EP,'' ''office visit,'' ''transitions of care,'' and ''referrals,'' we refer readers to the discussion at 77 FR 53982 through 53983. For eligible hospitals and CAHs, the references used to define the scope of the potential denominators for measures include the following:

• Unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department during the EHR reporting period.

• All medication, laboratory, and diagnostic imaging orders created during the reporting period.

• Transitions of care and referrals including at least—

++ When the hospital is the recipient of the transition or referral: all admissions to the inpatient and emergency departments; and

++ When the hospital is the initiator of the transition or referral: all discharges from the inpatient department; and after admissions to the emergency department when follow-up care is ordered by an authorized provider.

We propose that the explanation of the terms ''unique patients,'' ''transitions of care,'' and ''referrals'' stated previously for EPs would also apply for eligible hospitals and CAHs, and we refer readers to the discussion of those terms in the hospital context in the Stage 2 final rule (77 FR 53983 and 53984). We propose for Stage 3 to maintain the policy that admissions may be calculated using one of two methods (the observation services method and the all emergency department method), as described for Stage 2 at 77 FR 53984. The method an eligible hospital or CAH chooses must be used uniformly across all measures for all objectives.

We reiterate that all discharges from an inpatient setting are considered a transition of care. We further propose for transitions from an emergency department, that eligible hospitals and CAHs must count any discharge where follow up care is ordered by an authorized provider regardless of the completeness of information available on the receiving provider. The eligible hospital or CAH should determine an internal policy applicable for the identification and capture of a patient's primary care provider or other relevant care team members for the purposes of ordering potential follow-up care. This will allow eligible hospitals and CAHs to better differentiate between discharges where care is ordered and discharges to home where no follow up care is ordered.

(g) Patient-Authorized Representatives

In the Stage 3 Coordination of Care through Patient Engagement objective and the Patient Electronic Access objective outlined in section II.A.1.c.(2).(i). of this proposed rule, we propose the inclusion of patient-authorized representatives in the numerators as equivalent to the inclusion of the patient. We recognize that patients often consult with and rely on trusted family members and other caregivers to help coordinate care, understand health information, and make health care decisions. Accordingly, as part of these objectives, we encourage providers to provide access to health information to patient-authorized representatives in accordance with all applicable laws. We expect that patient-authorized representatives accessing such information under these objectives could include a wide variety of sources, including caregivers and various family members. However, we expect that patient-authorized representatives with access to such health information will always act on the patient's behalf and in the patient's best interests, and will remain free from any potential or actual conflict of interest with the patient. We further expect that the patient-authorized representatives would have the patient's best interests at heart and will act in a manner protective of the patient.

(h) Discussion of the Relationship of Meaningful Use to CEHRT

We propose to continue our policy of linking each meaningful use objective to the CEHRT definition and to ONC-established certification criteria. As with Stage 1 and Stage 2, EPs, eligible hospitals, and CAHs must use technology certified to the certification criteria in the ONC Health IT Certification Program to meet the objectives and associated measures for Stage 3 of meaningful use. In some instances, meaningful use objectives and measures may not be directly enabled by certification criteria of the Health IT Certification Program. For example, in e-Rx and public health reporting, the CEHRT definition requires criteria established by the Health IT Certification Program to be applied to the message being sent or received and for purposes of message transmission. However, to actually engage in e-Rx or public health reporting, there are many steps that must be taken to meet the requirements of the measure, such as contacting both parties and troubleshooting issues that may arise through the normal course of business. In these cases, the EP, eligible hospital, and CAH remain responsible for meeting the objectives and measures of meaningful use, but the way they do so is not entirely constrained by the CEHRT definition.

(i) Discussion of the Relationship Between a Stage 3 Meaningful Use Objective and Its Associated Measure

We propose to continue our Stage 1 and 2 policy that regardless of any actual or perceived gaps between the measure of an objective and full compliance with the objective, meeting the criteria of the measure means that the provider has met the objective for meaningful use in Stage 3.

Objective 1: Protect Patient Health Information

The Health Insurance Portability and Accountability Act (HIPAA) was enacted in part to provide federal protections for individually identifiable health information (IIHI). The Secretary of HHS adopted what are commonly known as the HIPAA Privacy, Security and Breach Notification Rules (HIPAA Rules) to implement certain aspects of the HIPAA statute and the HITECH statute pertaining to a patient's IIHI. The Privacy Rule provides protections for most individually identifiable health information, in any form or media, whether electronic, paper, or oral, held by covered entities and business associates. The Security Rule specifies a series of administrative, physical, and technical standards that provide protections for most electronic individually identifiable health information, held by covered entities and business associates. Covered entities consist of most health care providers, health plans, and health care clearinghouses. Business associates consist of persons or organizations that perform certain functions or activities on behalf of, or provide certain services to, covered entities or other business associates that involve the use or disclosure of individually identifiable health information. Individually identifiable health information is information that relates to an individual's physical or mental health or condition, the provision of health care to an individual, or the payment for the provision of health care to an individual. Individually identifiable health information is information that identifies an individual directly or with

respect to which there is a reasonable basis to believe it can be used to identify an individual. The individually identifiable health information protected by the HIPAA Rules is known as ''protected health information'' and that information in electronic form is known as ''electronic protected health information'' (ePHI). The Privacy Rule can be found at 45 CFR Part160 and subparts A and E of part 164 and the Security Rule can be found at 45 CFR Part160 and Subparts A and C of Part 164. Section 164.308(a)(1) of the Security Rule requires covered entities and business associates, among other things, to conduct a security risk analysis to assess the potential risks to the ePHI they create, receive, maintain, or transmit.

Consistent with HIPAA and its implementing regulations, and as we stated under both the Stage 1 and Stage 2 final rules (75 FR 44368 through 44369 and 77 FR 54002 through 54003), protecting ePHI remains essential to all aspects of meaningful use under the EHR Incentive Programs. We remain cognizant that unintended or unlawful disclosures of ePHI could diminish consumer confidence in EHRs and the overall exchange of ePHI. Therefore, in both the Stage 1 and 2 final rules, we created a meaningful use core objective aimed at protecting patients' health care information. Most recently, we finalized at (77 FR 54002 and 54003), a Stage 2 meaningful use core objective requiring providers to ''protect ePHI created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.'' The measure for this objective requires providers to conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of data stored in CEHRT in accordance with requirements under 45 CFR 164.312 (a)(2)(iv) and 45 CFR 164.306(d)(3), implementing security updates as necessary, and correcting identified security deficiencies as part of the provider's risk management process. For further detail on this objective, we refer readers to the Stage 2 proposed and final rules (77 FR 13716 through 13717 and 77 FR 54002).

In this Stage 3 proposed rule, we continue to emphasize the importance of protecting ePHI under the EHR Incentive Programs. With more and more users using electronic health records, we believe that adequate protection of ePHI remains instrumental to the continued success of the EHR Incentive Program.

However, public comments on the Stage 2 final rule and subsequent comments received through public forums, suggest some confusion remains among providers between the requirements of this meaningful use objective and the requirements established under 45 CFR 164.308(a)(1), 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3) of the HIPAA Security Rule. Although we stressed that the objective and measure finalized relating to ePHI are specific to the EHR Incentive Programs, and further added that compliance with the requirements in the HIPAA Security Rule falls outside the scope of this rulemaking, we nonetheless continued to receive inquiries about the relationship between our objective and the HIPAA Rules. Therefore, for Stage 3, in order to alleviate provider confusion and simplify the EHR Incentive Program, we are proposing to maintain the previously finalized Stage 2 objective on protecting ePHI. However, we propose further explanation of the security risk analysis timing and review requirements for purposes of meeting this objective and associated measure for Stage 3.

Proposed Objective: Protect electronic protected health information (ePHI) created or maintained by the certified EHR technology (CEHRT) through the implementation of appropriate technical, administrative, and physical safeguards.

For the proposed Stage 3 objective, we have added language to the security requirements for the implementation of appropriate technical, administrative, and physical safeguards. We propose to include administrative and physical safeguards because an entity would require technical, administrative, and physical safeguards to enable it to implement risk management security measures to reduce the risks and vulnerabilities identified. Technical safeguards alone are not enough to ensure the confidentiality, integrity, and availability of ePHI. Administrative safeguards (for example, risk analysis, risk management, training, and contingency plans) and physical safeguards (for example, facility access controls, workstation security) are also required to protect against threats and impermissible uses or disclosures to ePHI created or maintained by CEHRT.

Proposed Measure: Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data stored in CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.

Under this proposed measure, a risk analysis must assess the risks and vulnerabilities to ePHI created or maintained by the CEHRT and must be conducted or reviewed for each EHR reporting period, which, as proposed in this rule, would be a full calendar year, and any security updates and deficiencies identified should be included in the provider's risk management process and implemented or corrected as dictated by that process.

To address inquiries about the relationship between this measure and the HIPAA Security Rule, we explain that the requirement of this proposed measure is narrower than what is required to satisfy the security risk analysis requirement under 45 CFR 164.308(a)(1). The requirement of this proposed measure is limited to annually conducting or reviewing a security risk analysis to assess whether the technical, administrative, and physical safeguards and risk management strategies are sufficient to reduce the potential risks and vulnerabilities to the confidentiality, availability, and integrity of ePHI created by or maintained in CEHRT. In contrast, the security risk analysis requirement under 45 CFR 164.308(a)(1) must assess the potential risks and vulnerabilities to the confidentiality, availability, and integrity of all ePHI that an organization creates, receives, maintains, or transmits. This includes ePHI in all forms of electronic media, such as hard drives, floppy disks, CDs, DVDs, smart cards or other storage devices, personal digital assistants, transmission media, or portable electronic media.

We propose that the timing or review of the security risk analysis to satisfy this proposed measure must be as follows:

- EPs, eligible hospitals, and CAHs must conduct the security risk analysis upon installation of CEHRT or upon upgrade to a new Edition of certified EHR Technology. The initial security risk analysis and testing may occur prior to the beginning of the first EHR reporting period using that certified EHR technology.
- In subsequent years, a provider must review the security risk analysis of the CEHRT and the administrative, physical, and technical safeguards implemented, and make updates to its analysis as necessary, but at least once per EHR reporting period.

We note that providers have several resources available for strategies and

methods for securing ePHI. Completing a security risk analysis requires a time investment, and may necessitate the involvement of security, health IT, or system IT staff or support teams at your facility. The Office for Civil Rights (OCR) provides broad scale guidance on security risk analysis requirements at: *http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/rafinalguidancepdf.pdf.*

In addition, other tools and resources are available to assist providers in the process. For example, the Office of the National Coordinator for Health IT (ONC) provides guidance and a Security Risk Assessment (SRA) tool created in conjunction with OCR on its Web site at: *http://www.healthit.gov/providers-professionals/security-risk-assessment-tool.* The SRA Tool is a self-contained application available at no cost to the provider. There are a total of 156 questions and resources are included with each question to—

- Assist in understanding the context of the question
- Consider the potential impacts to ePHI if the requirement is not met
- See the actual safeguard language of the HIPAA Security Rule

In addition, the SRA Tool assists a provider by suggesting when corrective action may be required for a particular item. This tool is not required by the HIPAA Security Rule, but is one means by which providers and professionals in small and medium sized practices may perform a security risk analysis.

We further note that the 2015 Edition proposed rule published elsewhere in this issue of the **Federal Register** includes an auditable events and tamper-resistance criterion which is known as an ''audit log'' which can be a valuable resource in ensuring the protection of ePHI. While we recognize there may be legitimate instances where the function must be disabled for a short time, we strongly recommend providers ensure this function is enabled at all times when the CEHRT is in use. The audit log function serves to ensure consistent protection of ePHI as well as providing support in mitigating risk in other areas such as patient safety, adverse events, and in the event of any potential breach.

We emphasize that our discussion of this measure as it relates to 45 CFR 164.308(a)(1) is only relevant for purposes of the meaningful use requirements and is not intended to supersede or satisfy the broader, separate requirements under the HIPAA Security Rule and other rulemaking. Compliance with the requirements in the HIPAA Security Rule fall outside of the scope of this rulemaking. Compliance with 42 CFR part 2 and state mental health privacy and confidentiality laws also fall outside the scope of this rulemaking. EPs, eligible hospitals, or CAHs affected by 42 CFR part 2 should consult with the Substance Abuse and Mental Health Services Administration (SAMHSA) or State authorities.

We welcome public comments on this proposal.

Objective 2: Electronic Prescribing

For Stage 3, we propose to maintain the objective and measure finalized in the Stage 2 final rule for electronic prescribing for EPs, with minor changes. In the Stage 2 final rule, we included for eligible hospitals and CAHs a menu set objective for the electronic prescription of discharge medications. We are proposing to include the Stage 2 menu objective, with a modification to increase the threshold, as a required objective for Stage 3 of meaningful use for eligible hospitals and CAHs.

For a full discussion of electronic prescribing as a meaningful use objective in the Stage 2 final rule, we direct readers to (77 FR 53989 through 53990 for EPs and 77 FR 54035 through 54036 for eligible hospitals and CAHs).

Proposed Objective: EPs must generate and transmit permissible prescriptions electronically, and eligible hospitals and CAHs must generate and transmit permissible discharge prescriptions electronically (eRx).

As discussed in the Stage 2 final rule (77 FR 53989), transmitting the prescription electronically promotes efficiency and patient safety through reduced communication errors. It also allows the pharmacy or a third party to automatically compare the medication order to others they have received for the patient that works in conjunction with clinical decision support interventions enabled at the generation of the prescription. While the EP performance rate across all years and stages of participation indicate wide spread adoption, with the median rate at 89 percent for Stage 1 and 92 percent for Stage 2 [3], we believe continued support of this objective is warranted to support the continued development of the ePrescribing marketplace. The continued expansion of the number and variety of products helps to reduce entry barriers and proliferate important standards for ePrescribing for a wide range of providers beyond those eligible for the EHR Incentive Programs. This represents a benefit to patients and to population health through a potential overall reduction in the occurrence of prescription drug related adverse events. For eligible hospitals and CAHs, the performance rate among Stage 2 providers selecting the measure is higher than the 10 percent threshold and has increased since the previous report (median rate is 76 [4] percent). This opportunity to expand on early success, combined with the continued expansion of the pharmacy market acceptance of electronic prescriptions leads CMS to believe providers can meet an even higher threshold and should be encouraged to do so.

We propose to continue to define ''prescription'' as the authorization by a provider to dispense a drug that would not be dispensed without such authorization. This includes authorization for refills of previously authorized drugs. We propose to continue to generally define a ''permissible prescription'' as all drugs meeting the definition of prescription not listed as a controlled substance in Schedules II–V (DEA Web site at *http://www.deadiversion.usdoj.gov/schedules/index.html* (77 FR 53989) with a slight modification to allow for inclusion of scheduled drugs where such drugs are permissible to be electronically prescribed. We note that the electronic prescribing of controlled substances (EPCS) is now legal in many states. This functionality provides prescribers with a way to manage treatments for patients with pain electronically and also deters creation of fraudulent prescriptions, which is a major concern in combating opioid misuse and abuse. While the technology may, in many instances, be in place to support EPCS, workflow challenges and additional modifications may need to occur to meet the requirements of Drug Enforcement Agency regulations (75 FR 16236). However, as Stage 3 would not begin until January of 2017 and would not be required until January of 2018, it is possible that significant progress in the availability of products enabling the electronic prescribing of controlled substances may occur. Therefore, we are proposing that providers who practice in a state where controlled substances may be electronically prescribed who wish to include these prescriptions in the numerator and denominator may do so under the definition of ''permissible prescriptions'' for their practice. If a provider chooses to include such

[3] Data may be found on the CMS Web site data and program reports page: *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html.*

[4] Data may be found on the CMS Web site data and program reports page: *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html.*

prescriptions, they must do so uniformly across all patients and across all allowable schedules for the duration of the EHR reporting period.

For Stage 2, we requested comment on whether over-the-counter (OTC) medicines should be included in the definition of a prescription for this objective and determined that they should be excluded. For further information on that discussion, we direct readers to (77 FR 53989 and 53990). We maintain that OTC medicines will not be routinely electronically prescribed and propose to continue to exclude them from the definition of a prescription. However, we encourage public comment on this assumption and whether OTC medicines should be included in this objective for Stage 3.

In the Stage 2 final rule at (77 FR 53989), we discussed several different workflow scenarios that are possible when an EP prescribes a drug for a patient and that these differences in transmissions create differences in the need for standards. We propose to maintain this policy for Stage 3 for EPs and extend it to eligible hospitals and CAHs so that only a scenario in which a provider—

- Prescribes the drug;
- Transmits it to a pharmacy independent of the provider's organization; and
- The patient obtains the drug from that pharmacy requires the use of standards to ensure that the transmission meets the goals of electronic prescribing. In that situation, standards can ensure the whole process functions reliably. In all cases under this objective, the provider needs to use CEHRT as the sole means of creating the prescription, and when transmitting to an external pharmacy that is independent of the provider's organization, such transmission must be pursuant to ONC Health IT Certification Program criteria.

Proposed EP Measure: More than 80 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.

In Stage 1 of meaningful use, we adopted a measure of more than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using CEHRT. In the Stage 1 final rule (75 FR 44338), we acknowledged that there were reasons why a patient may prefer a paper prescription such as the desire to shop for the best price (especially for patients in the Part D ''donut hole''), the indecision about whether to have the prescription filled locally or by mail order, and the desire to use a manufacturer coupon (except in the Part D program) to obtain a discount.

In Stage 2, we adopted a measure of more than 50 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT. Our analysis of attestation data from Stages 1 and 2 shows that the median performance on this measure for Stage 1 EPs is 89 percent and for Stage 2 EPs is 92 percent, which demonstrates that the 50 percent threshold does not exceed the ceiling created by patient preferences [5]. We believe that with continued experience with this objective and the continued expansion of the pharmacy market acceptance of electronic prescriptions, providers can meet an even higher threshold and should be encouraged to do so in line with the statutory directive to seek to improve the use of EHRs and health care quality over time by requiring more stringent measures of meaningful use (see section 1848(o)(2)(A)(iii) of the Act). Therefore, we are proposing a threshold of 80 percent for this measure for Stage 3.

We propose to maintain for Stage 3 the exclusion from Stage 2 for EPs who write fewer than 100 permissible prescriptions during the EHR reporting period. We also propose to maintain for Stage 3 the exclusion from Stage 2 if no pharmacies within a 10-mile radius of an EP's practice location at the start of his or her EHR reporting period accept electronic prescriptions (77 FR 53990). This is 10 miles in any straight line from the practice location independent of the travel route from the practice location to the pharmacy. For EPs practicing at multiple locations, they are eligible for the exclusion if any of their practice locations equipped with CEHRT meet this criterion. An EP would not be eligible for this exclusion if he or she is part of an organization that owns or operates its own pharmacy within the 10-mile radius regardless of whether that pharmacy can accept electronic prescriptions from EPs outside of the organization.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

Denominator: Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the EHR reporting period or Number of prescriptions written for drugs requiring a prescription in order to be dispensed during the EHR reporting period.

Numerator: The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using CEHRT.

Threshold: The resulting percentage must be more than 80 percent in order for an EP to meet this measure.

Exclusions: Any EP who: (1) Writes fewer than 100 permissible prescriptions during the EHR reporting period; or (2) does not have a pharmacy within their organization and there are no pharmacies that accept electronic prescriptions within 10 miles of the EP's practice location at the start of his or her EHR reporting period.

Proposed Eligible Hospital/CAH Measure: More than 25 percent of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.

In the Stage 2 final rule, we included in this measure new, changed, and refill prescriptions ordered during the course of treatment of the patient while in the hospital (77 FR 54036). We are proposing to limit this measure for Stage 3 to only new and changed prescriptions. We believe this limitation is appropriate because prescriptions that originate prior to the hospital stay, and that remain unchanged, would be within the purview of the original prescriber, and not hospital staff or attending physicians. We propose to include this limitation as we believe that in most cases a hospital would not issue refills for medications that were not authorized or altered during a patient's hospital stay. With this new proposal, we invite public comment on whether a hospital would issue refills upon discharge for medications the patient was taking when they arrived at the hospital and, if so, whether distinguishing those refill prescriptions from new or altered prescriptions is unnecessarily burdensome for the hospital.

Our review of the Stage 2 attestation data for eligible hospitals and CAHs indicates performance levels of 53 percent at the median and 31 percent for the lowest quartile (*www.cms.gov/ehrincentiveprograms* Data and Reports). Thus, we are proposing to increase the threshold for the measure from 10 percent to 25 percent for Stage 3 of meaningful use for eligible hospitals and CAHs.

We propose to maintain the Stage 2 exclusion for any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic

[5] Data can be found on the CMS Web site data and program reports page: *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html.*

prescriptions and is not located within 10 miles of any pharmacy that accepts electronic prescriptions at the start of their EHR reporting period (77 FR 54036).

We recognize that not every patient will have a formulary that is relevant for him or her. If a relevant formulary is available, then the information can be provided. If there is no formulary for a given patient, the comparison could return a result of formulary unavailable for that patient and medication combination, and the provider may count the prescription in the numerator if they generate and transmit the prescription electronically as required by the measure.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

Denominator: The number of new or changed prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances for patients discharged during the EHR reporting period.

Numerator: The number of prescriptions in the denominator generated, queried for a drug formulary and transmitted electronically.

Threshold: The resulting percentage must be more than 25 percent in order for an eligible hospital or CAH to meet this measure.

Exclusion: Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of their EHR reporting period.

We invite public comment on these proposals.

Objective 3: Clinical Decision Support

Proposed Objective: Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

Clinical decision support at the relevant point of care is an area of health IT in which significant evidence exists for substantial positive impact on the quality, safety, and efficiency of care delivery. For Stage 2, we finalized an objective for the use of CDS to improve performance on high-priority health conditions, and two associated measures (77 FR 53995 through 53998). The first measure requires a provider to implement five CDS interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period. Absent four CQMs related to the provider's scope of practice or patient population, the CDS interventions must be related to high-priority health conditions. At least one of the CDS interventions should be related to improving healthcare efficiency. To meet the Stage 2 Clinical Decision Support objective, providers must implement the CDS intervention at a relevant point in patient care when the intervention can influence clinical decision making before an action is taken on behalf of the patient. Although we leave it to the provider's clinical discretion to determine the relevant point in patient care when such interventions will be most effective, the interventions must be presented through Certified EHR Technology to a licensed healthcare professional who can exercise clinical judgment about the decision support intervention before an action is taken on behalf of the patient. For the second measure, we consolidated the Stage 1 ''drug-drug/drug-allergy interaction checks'' objective into the Stage 2 CDS objective in the Stage 2 final rule (77 FR 53995 through 53998). The second measure requires a provider to enable and implement the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period. We also finalized an exclusion for the second measure for any EP who writes fewer than 100 medication orders during the EHR reporting period.

For Stage 3 of meaningful use, we propose to maintain the Stage 2 objective with slight modifications and further explanation of the relevant point of care, the types of CDS allowed, and the selection of a CDS applicable to a provider's scope of practice and patient population.

First, we offer further explanation of the concept of the relevant point of care and note that providers should implement the CDS intervention at a relevant point in clinical workflows when the intervention can influence clinical decision making before diagnostic or treatment action is taken in response to the intervention. Second, many providers may associate CDS with pop-up alerts; however, these alerts are not the only method of providing CDS. CDS should not be viewed as simply an interruptive alert, notification, or explicit care suggestion. Well-designed CDS encompasses a variety of workflow-optimized information tools, which can be presented to providers, clinical and support staff, patients, and other caregivers at various points in time. These may include but are not limited to: Computerized alerts and reminders for providers and patients; information displays or links; context-aware knowledge retrieval specifications which provide a standard mechanism to incorporate information from online resources (commonly referred to as InfoButtons); clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support; and contextually relevant reference information. These functionalities may be deployed on a variety of platforms (that is, mobile, cloud-based, installed).[6] We encourage innovative efforts to use CDS to improve care quality, efficiency, and outcomes. HIT functionality that builds upon the foundation of an EHR to provide persons involved in care processes with general and person-specific information, intelligently filtered and organized, at appropriate times, to enhance health and health care. CDS is not intended to replace clinician judgment, but rather, is a tool to assist care team members in making timely, informed, and higher quality decisions.

We propose to retain both measures of the Stage 2 objective for Stage 3 and we are proposing that these additional options mentioned previously on the actions, functions, and interventions may constitute CDS for purposes of meaningful use would meet the measure requirements outlined in the proposed measures.

Proposed Measures: EPs, eligible hospitals, and CAHs must satisfy both measures in order to meet the objective:

Measure 1: Implement five clinical decision support interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period. Absent four CQMs related to an EP, eligible hospital, or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions.

Measure 2: The EP, eligible hospital, or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

Exclusion: For the second measure, any EP who writes fewer than 100 medication orders during the EHR reporting period.

We recommend that providers explore a wide range of potential CDS interventions and determine the best mix for their practice and patient population. There are a wide range of CQMs which providers may implement in conjunction with the CDS. We refer readers to the CMS eCQM Library (*www.cms.gov/ehrincentiveprograms/ecqmlibrary*) for a list of the CQMs

[6] FDASIA Health IT report available on the FDA Web site at: *http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf.*

currently in use and under development for CMS programs and the associated National Quality Strategy domain categories.

In alignment with the HHS National Quality Strategy goals,[7] providers are encouraged to implement CDS related to quality measurement and improvement goals on the following areas:

- Preventive care.
- Chronic condition management.
- Heart disease and hypertension.
- Appropriateness of diagnostic orders or procedures such as labs, diagnostic imaging, genetic testing, pharmacogenetic and pharmacogenomic test result support or other diagnostic testing.
- Advanced medication-related decision support, to include pharmacogenetic and pharmacogenomic test result support.

An example of a potential CDS a provider may include which highlights the proposed expansion of the variety of workflow-optimized tools available for providers, and the link between a CDS and a high priority health condition, may be found in the use of treatment protocols and algorithms within the Million Hearts initiative. The Million Hearts initiative emphasizes the use of treatment protocols which can be embedded throughout the clinical workflow for hypertension control to standardize a team's or system's approach to achieving outcomes of interest. These treatment protocols or algorithms can expand the number of care team members that can assist in achieving desired outcomes; lend clarity, efficiency, and cost-effectiveness to selection of medications; and specify intervals and processes for patient follow up for care related to hypertension. For further information on this example, we direct readers to the Million Hearts initiative protocols *http://millionhearts.hhs.gov/resources/protocols.html*. In this example, these CDS interventions are applied to utilize standardized treatment approaches or protocols specific to hypertension control; however, we emphasize that similar strategies and approaches to the implementation of a variety of CDS can be widely applied. Another relevant example is clinical decision support in certified EHR technology that is used for consultation regarding appropriate use criteria for applicable imaging services as outlined in section 218 of the ''Protecting Access to Medicare Act of 2014'' which includes provisions focused on promoting evidence based care. We welcome public comments on the proposals.

As in the Stage 2 final rule (77 FR 53997), we do not propose to require the provider to report a change in performance on individual CQMs either independently or in relation to the paired CDS. Rather, we recommend each provider set internal goals for improved performance using the CQM, or related set of CQMs, as indicators for their own reference when selecting and implementing a CDS intervention. We note that for CDS and CQM pairings, we recommend providers focus on the use of CQMs which measure patient outcomes (also known as outcome measures), as preferred over CQMs which measure clinical process without consideration of a particular outcome (also known as process measures). Outcome measure CQMs are designed to provide a patient-centered and outcome-focused indicator for quality improvement goal-setting and planning. Where possible, we recommend providers implement CDS interventions which relate to care quality improvement goals and a related outcome measure CQM. However, for specialty hospitals and certain EPs, if there are no CQMs which are outcome measures related to their scope of practice, the provider should implement a CDS intervention related to a CQM process measure; or if none of the available CQMs apply, the provider should apply an intervention that he or she believes will be effective in improving the quality, safety, or efficiency of patient care.

CMS and ONC are committed to harmonizing the quality improvement ecosystem, refining and developing outcome measures, and aligning standards for CDS and quality measurement. Work is underway in the ONC Standards and Interoperability Framework to align and develop a shared quality improvement data model and technical expression standards for both CDS and quality measurement. Upon successful completion, such standards may be considered for inclusion in future quality measurement and certification rulemaking.

Given the wide range of CDS interventions currently available and the continuing development of new technologies, we do not believe that any EP, eligible hospital, or CAH would be unable to identify and implement five CDS interventions as previously described. Therefore, we do not propose any exclusion for the first measure of this objective.

Objective 4: Computerized Provider Order Entry

In the Stage 2 final rule, we expanded the use of computerized provider order entry (CPOE) from the Stage 1 objective requiring only medication orders to be entered using CPOE to include laboratory orders and radiology orders. For a full discussion of this expansion, we direct readers to (77 FR 53985 through 53989). We maintain CPOE continues to represent an opportunity for providers to leverage technology to capture these orders to reduce error and maximize efficiencies within their practice, therefore we are proposing to maintain the use of CPOE for these orders as an objective of meaningful use for Stage 3.

Proposed Objective: Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.

We propose to continue to define CPOE as the provider's use of computer assistance to directly enter clinical orders (for example, medications, consultations with other providers, laboratory services, imaging studies, and other auxiliary services) from a computer or mobile device. The order is then documented or captured in a digital, structured, and computable format for use in improving safety and efficiency of the ordering process.

We propose to continue our policy from the Stage 2 final rule that the orders to be included in this objective are medication, laboratory, and radiology orders as such orders are commonly included in CPOE implementation and offer opportunity to maximize efficiencies for providers. However, for Stage 3, we are proposing to expand the objective to include diagnostic imaging, which is a broader category including other imaging tests such as ultrasound, magnetic resonance, and computed tomography in addition to traditional radiology. This change addresses the needs of specialists and allows for a wider variety of clinical orders relevant to particular specialists to be included for purposes of measurement.

In Stage 3, we propose to continue the policy from the Stage 2 final rule at 77 FR 53986 that orders entered by any licensed healthcare professional or credentialed medical assistant would

[7] HHS National Quality Strategy: *http://www.ahrq.gov/workingforquality/*.

count toward this objective. A credentialed medical assistant may enter orders if they are credentialed to perform the duties of a medical assistant by a credentialing body other than the employer. If a staff member of the eligible provider is appropriately credentialed and performs assistive services similar to a medical assistant, but carries a more specific title due to either specialization of their duties or to the specialty of the medical professional they assist, orders entered by that staff member would be included in this objective. We further note that medical staff whose organizational or job title, or the title of their credential, is other than medical assistant may enter orders if these staff are credentialed to perform the equivalent duties of a credentialed medical assistant by a credentialing body other than their employer and perform such duties as part of their organizational or job title. We defer to the provider's discretion to determine the appropriateness of the credentialing of staff to ensure that any staff entering orders have the clinical training and knowledge required to enter orders for CPOE. This determination must be made by the EP or representative of the eligible hospital or CAH based on—

- Organizational workflows;
- Appropriate credentialing of the staff member by an organization other than the employing organization;
- Analysis of duties performed by the staff member in question; and
- Compliance with all applicable federal, state, and local laws and professional guidelines.

However, as stated in the Stage 2 final rule at 77 FR 53986, it is apparent that the prevalent time when CDS interventions are presented is when the order is entered into CEHRT, and that not all EHRs also present CDS when the order is authorized (assuming such a multiple step ordering process is in place). This means that the person entering the order would be required to enter the order correctly, evaluate a CDS intervention either using their own judgment or through accurate relay of the information to the ordering provider, and then either make a change to the order based on the information provided by the CDS intervention or bypass the intervention. The execution of this role represents a significant impact on patient safety; therefore, we continue to maintain for Stage 3 that a layperson is not qualified to perform these tasks. We believe that the order must be entered by a qualified individual. We further propose that if the individual entering the orders is not the licensed healthcare professional, the order must be entered with the direct supervision or active engagement of a licensed healthcare professional.

We propose to maintain for Stage 3 our existing policy for Stages 1 and 2 that the CPOE function should be used the first time the order becomes part of the patient's medical record and before any action can be taken on the order. The numerator of this objective also includes orders entered using CPOE initially when the patient record became part of the certified EHR. This does not include paper orders entered initially into the patient record and then transferred to CEHRT by other individuals at a later time, nor does it include orders entered into technology not compliant with the CEHRT definition and transferred into the CEHRT at a later time. In addition, based on the discussion in the Stage 2 final rule (77 FR 53986), we propose to maintain for Stage 3 that ''protocol'' or ''standing'' orders may be excluded from this objective. The defining characteristic of these orders is that they are not created due to a specific clinical determination by the ordering provider for a given patient, but rather are predetermined for patients with a given set of characteristics (for example, administer medication X and order lab Y for all patients undergoing a certain specific procedure or refills for given medication). We agree that this category of orders warrant different considerations than orders that are due to a specific clinical determination by the ordering provider for a specific patient. Therefore, we allow providers to exclude orders that are predetermined for a given set of patient characteristics or for a given procedure from the calculation of CPOE numerators and denominators. However, the exclusion of this type of order may not be a blanket policy for patients presenting with a specific diagnosis or symptom which requires the evaluation and determination of the provider for the order.

We propose to maintain the Stage 2 description of ''laboratory services'' as any service provided by a laboratory that could not be provided by a non-laboratory for the CPOE objective for Stage 3 (77 FR 53984). We also propose to maintain for Stage 3 the Stage 2 description of ''radiologic services'' as any imaging service that uses electronic product radiation (77 FR 53986). Even though we are proposing to expand the CPOE objective from radiology orders to all diagnostic imaging orders, this description would still apply for radiology services within the expanded objective.

We invite public comment on these proposals.

Proposed Measures: An EP, eligible hospital or CAH must meet all three measures.

Proposed Measure 1: More than 80 percent of medication orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry;

Proposed Measure 2: More than 60 percent of laboratory orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry; and

Proposed Measure 3: More than 60 percent of diagnostic imaging orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

We propose to continue a separate percentage threshold for all three types of orders: medication, laboratory, and diagnostic imaging. We continue to believe that an aggregate denominator cannot best capture differentiated performance on the individual order types within the objective, and therefore maintain a separate denominator for each order type. We propose to retain exclusionary criteria from Stage 2 for those EPs who so infrequently issue an order type specified by the measures (write fewer than 100 of the type of order), that it is not practical to implement CPOE for that order type.

Based on our review of attestation data from Stages 1 and 2 demonstrating provider performance on the CPOE measures, we propose to increase the threshold for medication orders to 80 percent and to increase the threshold for diagnostic imaging orders and laboratory orders to 60 percent. Median performance for Stage 1 on medication orders is 95 percent for EPs and 93 percent foreligible hospitals and CAHs. Stage 2 median performance on laboratory and radiology orders is 80 percent and 83 percent for eligible hospitals and CAHs and 100 percent for EPs for both measures.[8] We believe it is reasonable to expect the actual use of CPOE for medication orders to increase from 60 percent in Stage 2 to 80 percent in Stage 3 and the actual use of CPOE for diagnostic imaging and laboratory

[8] Data can be found on the CMS Web site data and program reports page: *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html.*

orders to increase from 30 percent in Stage 2 to 60 percent in Stage 3. We note that despite the expansion of the category for radiology orders to diagnostic imaging orders, we do not anticipate a negative impact on the ability of providers to meet the higher threshold as the adoption of the expanded functionality does not require additional workflow implementation and allows for inclusion of a wider range of orders already being captured by many providers. Therefore, for medication orders we propose the threshold at 80 percent and for diagnostic imaging and laboratory orders we propose the threshold at 60 percent for Stage 3.

In the Stage 2 final rule, we addressed the concern posed when calculating a denominator of all orders entered into the CEHRT while limiting the numerator to only those entered into CEHRT using CPOE (77 FR 53987 through 53988). Potentially, this would exclude those orders that are never entered into the CEHRT in any manner. The provider would be responsible for including those orders in their denominator. However, we believe that providers using CEHRT use it as the patient's medical record; therefore, an order not entered into CEHRT would be an order that is not entered into a patient's medical record. For this reason, we expect that orders given for patients that are never entered into the CEHRT to be few in number or non-existent. While our experience with both Stage 1 and Stage 2 of meaningful use has shown that a denominator of all orders created by the EP or in the hospital would not be unduly burdensome for providers and would create a better measurement for CPOE usage, particularly for EPs who infrequently order medications, this does not guarantee such a denominator would be feasible for all providers. We invite comments on whether to continue to allow, but not require, providers to limit the measure of this objective to those patients whose records are maintained using CEHRT.

Proposed Measure 1: To calculate the percentage, CMS and ONC have worked together to define the following for this measure:

Denominator: Number of medication orders created by the EP or authorized providers in the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of orders in the denominator recorded using CPOE.

Threshold: The resulting percentage must be more than 80 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP who writes fewer than 100 medication orders during the EHR reporting period.

Proposed Measure 2: To calculate the percentage, CMS and ONC have worked together to define the following for this measure:

Denominator: Number of laboratory orders created by the EP or authorized providers in the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of orders in the denominator recorded using CPOE.

Threshold: The resulting percentage must be more than 60 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP who writes fewer than 100 laboratory orders during the EHR reporting period.

Proposed Measure 3: To calculate the percentage, CMS and ONC have worked together to define the following for this measure:

Denominator: Number of diagnostic imaging orders created by the EP or authorized providers in the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of orders in the denominator recorded using CPOE.

Threshold: The resulting percentage must be more than 60 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP who writes fewer than 100 diagnostic imaging orders during the EHR reporting period.

We seek comment on if there are circumstances which might warrant an additional exclusion for an EP such as a situation representing a barrier to successfully implementing the technology required to meet the objective. We also seek comment on if there are circumstances where an eligible hospital or CAH which focuses on a particular patient population or specialty may have an EHR reporting period where the calculation results in a zero denominator for one of the measures, how often such circumstances might occur, and whether an exclusion would be appropriate.

An EP through a combination of meeting the thresholds and exclusions must satisfy all three measures for this objective. An eligible hospital or CAH must meet the thresholds for all three measures.

We welcome public comment on these proposals.

Objective 5: Patient Electronic Access to Health Information

The Stage 1 and Stage 2 final rules included a number of objectives focused on increasing patient access to health information and supporting provider and patient communication. These objectives include patient reminders (77 FR 54005 through 54007), patient-specific education resources (77 FR 54011 through 54012), clinical summaries of office visits (77 FR 53998 through 54002), secure messaging (77 FR 54031 through 54033), and the ability for patients to view, download, and transmit their health information to a third party (77 FR 54007 through 54011). For Stage 3, we generally identified two related policy goals within the overall larger goal of improved patient access to health information and patient-centered communication. The first is to ensure patients have timely access to their full health record and related important health information; and the second is to engage in patient-centered communication for care planning and care coordination. While these two goals are intricately linked, we see them as two distinct priorities requiring different foci and measures of success. For the first goal, we are proposing to incorporate the Stage 2 objectives related to providing patients with access to health information, including the objective for providing access for patients (or their authorized representatives) to view online, download, and transmit their health information and the objective for patient-specific education resources, into a new Stage 3 objective entitled, ''Patient Electronic Access'' (Objective 5), focused on using certified EHR technology to support increasing patient access to important health information. For the second goal, we are proposing an objective entitled Coordination of Care through Patient Engagement (Objective 6) incorporating the policy goals of the Stage 2 objectives related to secure messaging, patient reminders, and the ability for patients (or their authorized representatives) to view online, download, and transmit their health information using the functionality of the certified EHR technology.

In this Stage 3 Patient Electronic Access Objective, we are proposing to incorporate certain measures and objectives from Stage 2 into a single objective focused on providing patients with timely access to information related to their care. This proposed objective is a consolidation of the first measure of the Stage 2 Core Objective

for EPs of ''Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP'' and the Stage 2 Core Objective for EPs to ''Use clinically relevant information from CEHRT to identify patient-specific education resources and provide those resources to the patient.'' For eligible hospitals and CAHs, this proposed objective consolidates the first measure of the Stage 2 Core Objective for eligible hospitals/CAHs of ''Provide patients the ability to view online, download, and transmit information about a hospital admission'' and the Stage 2 Core Objective ''Use clinically relevant information from CEHRT to identify patient-specific education resources and provide those resources to the patient.'' For further discussion around the development of the Stage 2 objectives, we direct readers to the Stage 2 final rule at (77 FR 53973).

In Stage 2, there are objectives that allow providers to communicate and provide information to patients through paper-based means, such as clinical summaries of office visits and patient-specific education resources. Although these methods of communication and information exchange are embraced by many providers and patients and we continue to support their use, we will no longer require or allow providers to capture and calculate these actions or attest to these measures for meaningful use Stage 3. While we believe that providing patients access to health information in many formats is beneficial to patient-centered communication, care delivery, and quality improvement, meaningful use Stage 3 focuses exclusively on electronic, certified EHR technology supported communication.

We are also proposing to expand the options through which providers may engage with patients under the EHR Incentive Programs. Specifically, we are proposing an additional functionality, known as application-program interfaces (APIs), which would allow providers to enable new functionalities to support data access and patient exchange. An API is a set of programming protocols established for multiple purposes. APIs may be enabled by a provider or provider organization to provide the patient with access to their health information through a third-party application with more flexibility than often found in many current ''patient portals.'' From the provider perspective, using this option would mean the provider would not be required to separately purchase or implement a ''patient portal,'' nor would they need to implement or purchase a separate mechanism to provide the secure download and transmit functions for their patients because the API would provide the patient the ability to download or transmit their health information to a third party. If the provider elects to implement an API, the provider would only need to fully enable the API functionality, provide patients with detailed instructions on how to authenticate, and provide supplemental information on available applications which leverage the API. For further discussion on the technical requirements for APIs, we direct readers to the 2015 Edition proposed rule published elsewhere in this issue of the **Federal Register**. The certification criteria proposed by ONC would establish API criteria which would allow patients, through a third-party application, to pull certain components of their unique health data directly from the provider's CEHRT, and potentially could—on demand—pull such information from multiple providers caring for a patient. Therefore, we are proposing for the Patient Electronic Access objective to allow providers to enable API functionality in accordance with the proposed ONC requirements in the 2015 Edition proposed rule published elsewhere in this issue of the **Federal Register**.

From the patient perspective, an API enabled by a provider will empower the patient to receive information from their provider in the manner that is most valuable to that particular patient. Patients would be able to collect their health information from multiple providers and potentially incorporate all of their health information into a single portal, application, program, or other software. We also believe that provider-enabled APIs allow patients to control the manner in which they receive their health information while still ensuring the interoperability of data across platforms. In addition, we recognize that a large number of patients consult with and rely on trusted family members and other caregivers to help coordinate care, understand health information, and make decisions. Therefore, we encourage providers to provide access to health information to appropriately authorized patient representatives.

As some low-cost and free API functions already exist in the health IT industry, we expect third-party application developers to continue to create low-cost solutions that leverage APIs as part of their business models. Therefore, we encourage health IT system developers to leverage these existing API platforms and applications to allow providers no-cost, or low-cost solutions to implement and enable an API as part of their CEHRT systems. In addition, we do not believe it would be appropriate for EPs and hospitals to charge patients a fee for accessing their information using an API.

The goal of this objective is to allow patients easy access to their health information as soon as possible, so that they can make informed decisions regarding their care and share their most recent clinical information with other health care providers and personal caregivers as they see fit. We believe this is also integral to the hospital Partnership for Patients initiative and reducing hospital readmissions. This objective aligns with the Fair Information Practice Principles (FIPPS),[9] in affording baseline privacy protections to individuals.[10]

We seek comment on what additional requirements might be needed to ensure that if the eligible hospital, CAH or EP selects the API option—(1) the functionality supports a patient's right to have his or her protected health information sent directly to a third party designated by the patient; and (2) patients have at least the same access to and use of their health information that they have under the view, download, and transmit option.

Proposed Objective: The EP, eligible hospital, or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability.

We continue to believe that patient access to their electronic health

[9] 1 In 1973, the Department of Health, Education, and Welfare (HEW) released its report, *Records, Computers, and the Rights of Citizens,* which outlined a Code of Fair Information Practices that would create ''safeguard requirements'' for certain ''automated personal data systems'' maintained by the Federal Government. This Code of Fair Information Practices is now commonly referred to as fair information practice principles (FIPPs) and established the framework on which much privacy policy would be built. There are many versions of the FIPPs; the principles described here are discussed in more detail in *The Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information,* December 15, 2008. *http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_privacy_security_framework/1173.*

[10] The FIPPs, developed in the United States nearly 40 years ago, are well-established and have been incorporated into both the privacy laws of many states with regard to government-held records 2 and numerous international frameworks, including the development of the OECD's privacy guidelines, the European Union Data Protection Directive, and the Asia-Pacific Economic Cooperation (APEC) Privacy Framework. *http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_privacy_security_framework/1173.*

information is a high priority for the EHR Incentive Programs. Furthermore, providing educational resources about a patient's health including recommendations for preventative care and screenings, identifying risk factors, and other important health resources can help to increase patient health literacy, empower patients to make more informed decisions, and support the efforts of providers in managing a patient care plan. We also believe that patient access to health information should be provided in the manner requested by the patient when possible.

We note that for this objective, the provider is only required to provide access to the information through these means; the patient is not required to take action in order for the provider to meet this objective. In the Patient Electronic Access to Health Information objective, we note that ''provides access'' means that the patient has all the tools they need to gain access to their health information including any necessary instructions, user identification information, or the steps required to access their information if they have previously elected to ''opt-out'' of electronic access. If this information is provided to the patient in a clear and actionable manner, the provider may count the patient for this objective. Additionally, this objective should not require the provider to make extraordinary efforts to assist patients in use or access of the information, but the provider must inform patients of these options, and provide sufficient guidance so that all patients could leverage this access. The providers may withhold from online disclosure any information either prohibited by federal, state, or local laws or if such information provided through online means may result in significant harm. We also note, as we have previously, that this is a meaningful use requirement, which does not affect an individual's right under HIPAA to access his or her health information. Providers must continue to comply with all applicable requirements under the HIPAA Privacy Rule, including the access provisions of 45 CFR 164.524.

Proposed Measures: EPs, eligible hospitals, and CAHs must satisfy both measures in order to meet the objective:

Proposed Measure 1: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

(1) The patient (or patient-authorized representative) is provided access to view online, download, and transmit their health information within 24 hours of its availability to the provider; or

(2) The patient (or patient-authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient-authorized representatives) access to their health information, within 24 hours of its availability to the provider.

Proposed Measure 2: The EP, eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

We propose that for measure 1, the patient must be able to access this information on demand, such as through a patient portal, personal health record (PHR), or API and have everything necessary to access the information even if they opt out. All three functionalities (view, download, and transmit) or an API must be present and accessible to meet the measure. The functionality must support a patient's right to have his or her protected health information sent directly to a third party designated by the patient consistent with the provision of access requirements at 45 CFR 164.524(c) of the HIPAA Privacy Rule.

However, if the provider can demonstrate that at least one application that leverages the API is available (preferably at no cost to the patient) and that more than 80 percent of all unique patients have been provided instructions on how to access the information; the provider need not create, purchase, or implement redundant software to enable view, download, and transmit capability independently of the API.

We propose to increase the threshold for measure 1 from the Stage 1 and Stage 2 threshold of 50 percent to a threshold of 80 percent for Stage 3. We believe that all patients should be provided access to their electronic health record; however, we are setting the threshold at 80 percent based on the highest threshold defined for measures based on unique patients seen by the provider during the EHR reporting period in the Stage 2 final rule (for example see 77 FR 53993). Based on the continued progress toward automation and standardization of data capture supported by CEHRT which facilitates a faster response time, we further propose to decrease patient wait time for the availability of information to within 24 hours of the office visit or of the information becoming available to the provider for potential inclusion in the case of lab or other test results which require sufficient time for processing and returning results.

For measure 2, we propose to increase the threshold that was finalized in Stage 2 from 10 percent to 35 percent. We believe that the 35 percent threshold both ensures that providers are using CEHRT to identify patient-specific education resources and is low enough to not infringe on the provider's freedom to choose education resources and to which patients these resources will be provided.

We continue to propose that both measures for this objective must be met using CEHRT. For the purposes of meeting this objective, this would mean the capabilities provided by a patient portal, PHR, or any other means of online access that would permit a patient or authorized representatives to view, download, and transmit their personal health information and/or any API enabled, must be certified in accordance with the certification requirements adopted by ONC.

We are proposing a continuation of the exclusion in Stage 2 for both EPs and eligible hospitals/CAHs in that any EP, eligible hospital, or CAH would be excluded from the first measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period. We continue to recognize that in areas of the country where a significant section of the patient population does not have access to broadband internet, this measure may be significantly harder or impossible to achieve. Finally, we propose an additional exclusion for EPs for Stage 3, that any EP who has no office visits during the EHR reporting period may be excluded from the measures. We encourage comments on these exclusions and will evaluate them again in light of the public comments received.

Proposed Measure 1: To calculate the percentage, CMS and ONC have worked together to define the following for this measure:

Denominator: The number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of patients in the denominator who are provided access to information within 24 hours of its availability to the EP or eligible hospital/CAH.

Threshold: The resulting percentage must be more than 80 percent in order for a provider to meet this measure.

Exclusions: An EP may exclude from the measure if they have no office visits during the EHR reporting period.

Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the measure.

Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Proposed Measure 2: To calculate the percentage, CMS and ONC have worked together to define the following for this measure:

Denominator: The number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of patients in the denominator who were provided electronic access to patient-specific educational resources using clinically relevant information identified from CEHRT.

Threshold: The resulting percentage must be more than 35 percent in order for a provider to meet this measure.

Exclusions: An EP may exclude from the measure if they have no office visits during the EHR reporting period.

Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the measure.

Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Alternate Proposals:

We note that for measure one we are seeking comment on the following set of alternate proposals for providers to meet the measure using the functions of CEHRT outlined previously in this section. These alternate proposals involve the requirements to use a view, download, and transmit function or an API to provide patients access to their health information. We believe the current view, download, and transmit functions are widely in use and represent the current standard for patient access to their health record. However, we believe that the use of APIs could potentially replace this function and move toward a more accessible means for patients to access their information. Therefore, we are seeking comment on alternatives which would present a different mix of CEHRT functionality for providers to use for patients seeking to access their records. The proposed first measure discussed previously would allow providers the option either to give patients access to the view, download, and transmit functionality, or to give patients access to an API. Specifically, we are seeking comment on whether the API option should be required rather than optional for providers, and if so, should providers also be required to offer the view, download, and transmit function.

Proposed Measure 1: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

(1) The patient (or patient-authorized representative) is provided access to view online, download, and transmit their health information within 24 hours of its availability to the provider; or

(2) The patient (or the patient-authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient authorized representatives) access to their health information, within 24 hours of its availability to the provider.

Alternate A: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

(1) The patient (or the patient-authorized representative) is provided access to view online, download, and transmit his or her health information within 24 hours of its availability to the provider; and

(2) The patient (or patient-authorized representatives) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient authorized representatives) access to their health information within 24 hours of its availability to the provider.

Alternate B: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

(1) The patient (or patient-authorized representative) is provided access to view online, download, and transmit their health information within 24 hours of its availability to the provider; and the patient (or patient-authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient authorized representatives) access to their health information within 24 hours of its availability to the provider; or,

(2) The patient (or patient-authorized representatives) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient authorized representatives) access to their health information within 24 hours of its availability to the provider.

Alternate C: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), the patient (or patient-authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient-authorized representatives) access to their health information, within 24 hours of its availability to the provider.

These three alternate proposals would represent different use cases for the CEHRT function to support view, download, and transmit and/or API functionality. We note that under these proposed alternates the following mix of functions would be applicable: Alternate A would require both functions to be available instead of allowing the provider to choose between the two; Alternate B would require the provider to choose to have either both functions, or just an API function; and Alternate C would require the provider to only have the API function. For Alternate C, the use of a separate view, download, and transmit function would be entirely at the provider's discretion and not included as part of the definition of meaningful use.

We welcome public comment on these proposals.

Objective 6: Coordination of Care Through Patient Engagement

As mentioned previously, the Stage 1 and Stage 2 final rules included a number of objectives focused on patient access to health information and communication among providers, care teams, and patients. These patient engagement objectives focused on changing behaviors among providers and patients to promote patient

involvement in health care. Specifically, the objectives included supporting provider and patient communication about their health, improving overall patient health literacy, and supporting patient-driven coordination with providers and other members of the patient's care team. The Stage 1 and Stage 2 objectives included patient reminders (77 FR 54005 through 54007), patient-specific education resources (77 FR 54011 through 54012), clinical summaries of office visits (77 FR 53998 through 54002), secure messaging (77 FR 54031 through 54033), and the ability for patients to view, download, and transmit their health information to a third party (77 FR 54007 through 54011). For Stage 3, as mentioned previously, we are proposing to incorporate the Stage 2 objectives related to providing patients with access to health information into a new Stage 3 objective entitled, ''Patient Electronic Access'' (Objective 5). For the proposed objective entitled Coordination of Care through Patient Engagement (Objective 6), we are proposing to incorporate the policy goals of the Stage 2 objectives related to secure messaging, patient reminders, and the measure of patient engagement requiring patients (or their authorized representatives) to view, download, and transmit their health information using the functionality of the certified EHR technology.

As mentioned previously, while we believe there may be many methods of communication and information sharing among providers, or other care team members, and patients (including paper-based or telephone communications), meaningful use Stage 3 focuses exclusively on electronic, certified EHR technology supported communication in the requirements outlined in this proposed objective for Coordination of Care through Patient Engagement.

Proposed Objective: Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.

Specifically, this proposed rule focuses on encouraging the use of EHR functionality for secure dialogue and efficient communication between providers, care team members, and patients about their care and health status, as well as important health information such as preventative and coordinated care planning. In addition, certified EHR technology functions designed to support patient engagement can be a platform to securely capture and record patient-generated health data and information provided in non-clinical care settings.

We are also proposing to expand the options through which providers may engage with patients under the EHR Incentive Programs including the use of APIs as mentioned previously. An API can enable a patient—through a third-party application—to access and retrieve their health information from a care provider in a way that is most valuable to that particular patient.

Therefore, we are proposing a meaningful use objective for Stage 3 to support this provider and patient engagement continuum based on the foundation already created within the EHR Incentive Programs but using new methods and expanded options to advance meaningful patient engagement and patient-centered care. We also propose that for purposes of this objective, patient engagement may include patient-centered communication between and among providers facilitated by authorized representatives of the patient and of the EP, eligible hospital, or CAH. As care delivery evolves, the participation of a diverse group of care team members enables more robust care for the patient. Engagement between the patient and, for example, nutritionists, social workers, physical therapists, or other members of the provider's care team is crucial to effective patient engagement and are therefore included in this objective.

For Stage 3 of meaningful use, we propose the following measures for the Patient Engagement Objective:

Proposed Measures: We are proposing that providers must attest to the numerator and denominator for all three measures, but would only be required to successfully meet the threshold for two of the three proposed measures to meet the Coordination of Care through Patient Engagement Objective. These three measures support the communication continuum between providers, patients, and the patient's authorized representatives through the use of view, download, and transmit functionality. They also support using API functionality through patient engagement with their health data, but also potentially through secure messaging functions and standards, and the capture and inclusion of data collected from non-clinical settings, including patient-generated health data.

Proposed Measure 1: During the EHR reporting period, more than 25 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the electronic health record made accessible by the provider. An EP, eligible hospital or CAH may meet the measure by either:

(1) More than 25 percent of all unique patients (or patient-authorized representatives) seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period view, download or transmit to a third party their health information; or

(2) More than 25 percent of all unique patients (or patient-authorized representatives) seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period access their health information through the use of an ONC-certified API that can be used by third-party applications or devices.

Proposed Measure 2: For more than 35 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient's authorized representatives), or in response to a secure message sent by the patient (or the patient's authorized representative).

Proposed Measure 3: Patient-generated health data or data from a non-clinical setting is incorporated into the certified EHR technology for more than 15 percent of all unique patients seen by the EP or discharged by the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

For measure 1, we are proposing to increase the threshold for the measure from 5 percent to 25 percent based on provider performance on the related Stage 2 measure requiring more than 5 percent of patients to view, download, or transmit to a third party the health information made available to them by the provider. Stage 2 median performance for an EP on this measure is 32 percent and 11 percent for eligible hospitals.[11] Therefore, we are proposing more than 25 percent of all unique patients (or the patient's authorized representatives) seen by the EP, eligible hospital or CAH during the EHR reporting period must view, download, or transmit to a third party their health information or access their health information through the use of an ONC-certified API that can be used by third-party applications or devices. For the API option, we propose that providers must attest that they have enabled an API and that at least one application

[11] Data can be found on CMS Web site Data and Program Reports page: *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html.*

which leverages the API is available to patients (or the patient-authorized representatives) to retrieve health information from the provider's certified EHR.

CMS recognizes that there may be inherent challenges in measuring patient access to CEHRT through third-party applications that utilize an ONC-certified API, and we solicit comment on the nature of those challenges and what solutions can be put in place to overcome them. For example, are there specific requirements around the use of APIs or are there specific certification requirements for APIs that could make the measurement of this objective easier. We also solicit comment on suggested alternate proposals for measuring patient access to CEHRT through third-party applications that utilize an API, including the pros and cons of measuring a minimum number of patients (one or more) who must access their health information through the use of an API in order to meet the measure of this objective.

For measure 2, the EP, eligible hospital, CAH, or the provider's authorized representative must communicate with the patient (or the patient's authorized representatives), through secure electronic messaging for more than 35 percent of the unique patients seen by the provider during the EHR reporting period. ''Communicate'' means when a provider sends a message to a patient (or the patient's authorized representatives) or when a patient (or the patient's authorized representatives) sends a message to the provider. In patient-to-provider communication, the provider must respond to the patient (or the patient's authorized representatives) for purposes of this measure. We propose to increase the threshold for this measure over the threshold for the Stage 2 measure because for Stage 3 provider initiated messages would count toward the measure numerator.

For measure 2, we propose to include in the measure numerator situations where providers communicate with other care team members using the secure messaging function of certified EHR technology, and the patient is engaged in the message and has the ability to be an active participant in the conversation between care providers. However, we seek comment on how this action could be counted in the numerator, and the extent to which that interaction could or should be counted for eligible providers engaged in the communication. For example, should only the initiating provider be allowed to include the communication as an action in the numerator? Or, should any provider who contributes to such a message during the EHR reporting period be allowed to count the communication? In addition, we seek comment on what should be considered a contribution to the patient-centered communication; for example, a contribution must be active participation or response, a contribution may be viewing the communication, or a contribution may be simple inclusion in the communication.

We specify that the secure messages sent should contain relevant health information specific to the patient in order to meet the measure of this objective. We believe the provider is the best judge of what health information should be considered relevant in this context. For the purposes of this measure, we are proposing that secure messaging content may include, but is not limited to, questions about test results, problems, and medications; suggestions for follow-up care or preventative screenings; confirmations of diagnosis and care plan goals; and information regarding patient progress. However, we note that messages with content exclusively relating to billing questions, appointment scheduling, or other administrative subjects should not be included in the numerator. For care team secure messaging with the patient included in the conversation, we also believe the provider may exercise discretion if further communications resulting from the initial action should be excluded from patient disclosure to prevent harm. We note that if such a message is excluded, all subsequent actions related to that message would not count toward the numerator.

For measure 3, EPs, eligible hospitals, and CAHs (or their authorized representatives) must incorporate health data obtained from a non-clinical setting in a patient's electronic health record for more than 15 percent of unique patients seen during the EHR reporting period. We note that the use of the term ''clinical'' means different things in relation to place of service for billing for Medicare and Medicaid services. However, for purposes of this measure only, we are proposing that a non-clinical setting shall be defined as a setting with any provider who is not an EP, eligible hospital or CAH as defined for the Medicare and Medicaid EHR Incentive Programs. Therefore, for this measure, a non-clinical setting is any provider or setting of care which is not an EP, eligible hospital, or CAH in either the Medicare or Medicaid EHR Incentive Programs and where the care provider does not have shared access to the EP, eligible hospital, or CAHs certified EHR. This may include, but is not limited to, health and care-related data from care providers such as nutritionists, physical therapists, occupational therapists, psychologists, and home health care providers as well as data obtained from patients themselves. We specifically mention this last item and refer to this sub-category as patient-generated health data, which may result from patient self-monitoring of their health (such as recording vital signs, activity and exercise, medication intake, and nutrition), either on their own, or at the direction of a member of the care team. We are proposing this measure in response to requests from providers to support the capture and incorporation of patient-generated health data, and the capture and incorporation of data from a non-clinical setting into an EHR. Providers have expressed a desire to have this information captured in a useful and structured way and made available in the EHR. The capture and incorporation of this information is an integral part of ensuring that providers and patients have adequate information to partner in making clinical care decisions, especially for patients with chronic disease and complex health conditions for whom self-monitoring is an important part of an ongoing care plan.

We are seeking comment on how the information for measure 3 could be captured, standardized, and incorporated into an EHR. For the purposes of this measure, the types of data that would satisfy the measure is broad. It may include, but is not limited to social service data, data generated by a patient or a patient's authorized representatives, advance directives, medical device data, home health monitoring data, and fitness monitor data. In addition, the sources of data vary and may include mobile applications for tracking health and nutrition, home health devices with tracking capabilities such as scales and blood pressure monitors, wearable devices such as activity trackers or heart monitors, patient reported outcome data, and other methods of input for patient and non-clinical setting generated health data. We emphasize that these represent several examples of the data types that could be covered under this measure. We also note that while the scope of data covered by this measure is broad, it may not include data related to billing, payment, or other insurance information. As part of determining the proper scope of this measure, we are seeking comment on the following questions:

- Should the data require verification by an authorized provider?

• Should the incorporation of the data be automated?

• Should there be structured data elements available for this data as fields in an EHR?

• Should the data be incorporated in the CEHRT with or without provider verification?

• Should the provenance of the data be recorded in all cases and for all types of data?

We also seek comment on whether this proposed measure should have a denominator limited to patients with whom the provider has multiple encounters, such as unique patients seen by the provider two or more times during the EHR reporting period. We also seek comment on whether this measure should be divided into two distinct measures. The first measure would include only the specific sub-category of patient-generated health data, or data generated predominantly through patient self-monitoring rather than by a provider. The second measure would include all other data from a non-clinical setting. This would result in the objective including four measures with providers having an option of which two measures to focus on for the EHR reporting period.

We also seek comment on whether the third measure should be proposed for eligible hospitals and CAHs, or remain an option only for eligible professionals. For those commenters who believe it should not be applicable for eligible hospitals and CAHs, we seek further comment on whether eligible hospitals and CAHs should then choose one of the remaining two measures or be required to attest to both.

Providers must attest to the numerator and denominator for all three measures, and must meet the threshold for two of the three measures to meet the objective for Stage 3 of meaningful use:

Proposed Measure 1: We have identified the following for measure 1 of this objective:

Option 1: View, Download, or Transmit to a Third Party

Denominator: Number of unique patients seen by the EP, or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of unique patients (or their authorized representatives) in the denominator who have viewed online, downloaded, or transmitted to a third party the patient's health information.

Threshold: The resulting percentage must be more than 25 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Option 2: API

Denominator: The number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of unique patients (or their authorized representatives) in the denominator who have accessed their health information through the use of an an ONC-certified API.

Threshold: The resulting percentage must be more than 25 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusions: Applicable for either option discussed previously, the following providers may exclude from the measure:

Any EP who has no office visits during the EHR reporting period may exclude from the measure.

Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measure.

Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measure.

Measure 2: *Denominator:* Number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of patients in the denominator for whom a secure electronic message is sent to the patient, the patient's authorized representatives, or in response to a secure message sent by the patient.

Threshold: The resulting percentage must be more than 35 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP who has no office visits during the EHR reporting period may exclude from the measure.

Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measure.

Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measure.

Measure 3: *Denominator:* Number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of patients in the denominator for whom data from non-clinical settings, which may include patient-generated health data, is captured through the certified EHR technology into the patient record.

Threshold: The resulting percentage must be more than 15 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP who has no office visits during the EHR reporting period may exclude from the measure.

Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measure.

Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measure.

We seek comment on this proposed objective and the related proposed measures.

Objective 7: Health Information Exchange

Improved communication between providers caring for the same patient can help providers make more informed care decisions and coordinate the care they provide. Electronic health records and the electronic exchange of health information, either directly or through health information exchanges, can reduce the burden of such communication. The purpose of this objective is to ensure a summary of care record is transmitted or captured electronically and incorporated into the EHR for patients seeking care among

different providers in the care continuum, and to encourage reconciliation of health information for the patient. This objective promotes interoperable systems and supports the use of CEHRT to share information among care teams.

Proposed Objective: The EP, eligible hospital, or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of certified EHR technology.

In the Stage 2 final rule at 77 FR 53983, we described transitions of care as the movement of a patient from one setting of care (hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home health, rehabilitation facility) to another. Referrals are cases where one provider refers a patient to another provider, but the referring provider also continues to provide care to the patient. In this rule, we also recognize there may be circumstances when a patient refers himself or herself to a setting of care without a provider's prior knowledge or intervention. These referrals may be included as a subset of the existing referral framework and they are an important part of the care coordination loop for which summary of care record exchange is integral. Therefore, a provider should include these instances in their denominator for the measures if the patient subsequently identifies the provider from whom they received care. In addition, the provider may count such a referral in the numerator for each measure if they undertake the action required to meet the measure upon disclosure and identification of the provider from whom the patient received care.

In the Stage 2 final rule, we indicated that a transition or referral within a single setting of care does not qualify as a transition of care (77 FR 53983). We received public comments and questions requesting clearer characterization of when a setting of care can be considered distinct from another setting of care. For example, questions arose whether EPs who work within the same provider practice are considered the same or two distinct settings of care. Similarly, questions arose whether an EP who practices in an outpatient setting that is affiliated with an inpatient facility is considered a separate entity. Therefore, for the purposes of distinguishing settings of care in determining the movement of a patient, we explain that for a transition or referral, it must take place between providers which have, at the minimum, different billing identities within the EHR Incentive Programs, such as a different National Provider Identifiers (NPI) or hospital CMS Certification Numbers (CCN) to count toward this objective.

Please note that a ''referral'' as defined here and elsewhere in this proposed rule only applies to the EHR Incentive Programs and is not applicable to other federal regulations.

We stated in the Stage 2 proposed rule at 77 FR 13723 that if the receiving provider has access to the medical record maintained by the provider initiating the transition or referral, then the summary of care record would not need to be provided and that patient may be excluded from the denominators of the measures for the objective. We further note that this access may vary from read-only access of a specific record, to full access with authoring capabilities, depending on provider agreements and system implementation among practice settings. In many cases, a clinical care summary for transfers within organizations sharing access to an EHR may not be necessary, such as a hospital sharing their CEHRT with affiliated providers in ambulatory settings who have full access to the patient information. However, public comments received and questions submitted by the public on the Stage 2 Summary of Care Objective reveal that there may be benefits to the provision of a summary of care document following a transition or referral of a patient, even when access to medical records is already available. For example, a summary of care document would notify the receiving provider of relevant information about the latest patient encounter as well as highlight the most up-to-date information. In addition, the ''push'' of a summary of care document may function as an alert to the recipient provider of the transition that a patient has received care elsewhere and would encourage the provider to review a patient's medical record for follow-up care or reconciliation of clinical information.

Therefore, we are revising this objective for Stage 3 to allow the inclusion of transitions of care and referrals in which the recipient provider may already have access to the medical record maintained in the referring provider's CEHRT, as long as the providers have different billing identities within the EHR Incentive Program. We note that for a transition or referral to be included in the numerator, if the receiving provider already has access to the CEHRT of the initiating provider of the transition or referral, simply accessing the patient's health information does not count toward meeting this objective. However, if the initiating provider also sends a summary of care document, this transition can be included in the denominator and the numerator, as long as this transition is counted consistently across the organization.

Proposed Measures: We are proposing that providers must attest to the numerator and denominator for all three measures, but would only be required to successfully meet the threshold for two of the three proposed measures to meet the Health Information Exchange Objective.

Proposed Measure 1: For more than 50 percent of transitions of care and referrals, the EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care: (1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.

Proposed Measure 2: For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, eligible hospital or CAH incorporates into the patient's EHR an electronic summary of care document from a source other than the provider's EHR system.

Proposed Measure 3: For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, eligible hospital, or CAH performs a clinical information reconciliation. The provider must implement clinical information reconciliation for the following three clinical information sets:

- *Medication.* Review of the patient's medication, including the name, dosage, frequency, and route of each medication.
- *Medication allergy.* Review of the patient's known allergic medications.
- *Current Problem list.* Review of the patient's current and active diagnoses.

For the first measure, we are maintaining the requirements established in the Stage 2 final rule to capture structured data within the certified EHR and to generate a summary of care document using CEHRT for purposes of this measure (77 FR 54014). For purposes of this measure, we are requiring that the summary of care document created by CEHRT be sent electronically to the receiving provider.

In the Stage 2 final rule at 77 FR 54016, we specified all summary of care documents must include the following

information in order to meet the objective, if the provider knows it:

- Patient name.
- Referring or transitioning provider's name and office contact information (EP only).
- Procedures.
- Encounter diagnosis.
- Immunizations.
- Laboratory test results.
- Vital signs (height, weight, blood pressure, BMI).
- Smoking status.
- Functional status, including activities of daily living, cognitive and disability status.
- Demographic information (preferred language, sex, race, ethnicity, date of birth).
- Care plan field, including goals and instructions.
- Care team including the primary care provider of record and any additional known care team members beyond the referring or transitioning provider and the receiving provider.
- Discharge instructions (Hospital Only).
- Reason for referral (EP only).

For the 2015 Edition proposed rule, ONC has proposed a set of criteria called the Common Clinical Data Set which include the required elements for the summary of care document, the standards required for structured data capture of each, and further definition of related terminology and use. Therefore, for Stage 3 of meaningful use we are proposing that summary of care documents used to meet the Stage 3 Health Information Exchange objective must include the requirements and specifications included in the Common Clinical Data Set (CCDS) specified by ONC for certification to the 2015 Edition proposed rule published elsewhere in this issue of the **Federal Register**.

We note that ONC's 2015 Edition proposed rule may include additional fields beyond those initially required for Stage 2 of meaningful use as new standards have been developed to accurately capture vital information on patient health. For example, the 2015 Edition proposed rule includes a criterion and standard for capturing the unique device identifier (UDI) for implantable medical devices. The inclusion of the UDI in the CCDS reflects the understanding that UDIs are an important part of patient information that should be exchanged and available to providers who care for patients with implanted medical devices. Hundreds of thousands of Medicare beneficiaries receive some type of implantable medical device each year. Some implants require ongoing monitoring and medication for the device to perform effectively, such as a mechanical heart valve. Other implanted devices are affected by imaging procedures and are not MRI safe such as some pace makers. Even the variation between specific makes and models of similar devices may impact the clinical processes required to mitigate against patient safety risk. Without readily available data, the patient is put at risk if the provider does not have adequate knowledge of the existence and specific details of medical implants. Therefore, the documentation of UDIs in a patient medical record and the inclusion of that data field within the CCDS requirements for the summary of care documents is a key step toward improving the quality of care and ensuring patient safety. This example highlights the importance of capturing health data in a structured format using specified, transferable standards.

In circumstances where there is no information available to populate one or more of the fields included in the CCDS, either because the EP, eligible hospital, or CAH can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example, laboratory tests), the EP, eligible hospital, or CAH may leave the field blank and still meet the requirements for the measure.

However, all summary of care documents used to meet this objective must be populated with the following information using the CCDS certification standards for those fields:

- Current problem list (Providers may also include historical problems at their discretion).
- A current medication list.
- A current medication allergy list.

We define allergy as an exaggerated immune response or reaction to substances that are generally not harmful. Information on problems, medications, and medication allergies could be obtained from previous records, transfer of information from other providers (directly or indirectly), diagnoses made by the EP or hospital, new medications ordered by the EP or in the hospital, or through querying the patient.

We propose to maintain that all summary of care documents contain the most recent and up-to-date information on all elements. In the event that there are no current diagnoses for a patient, the patient is not currently taking any medications, or the patient has no known medication allergies; the EP, eligible hospital, or CAH must record or document within the required fields that there are no problems, no medications, or no medication allergies recorded for the patient to satisfy the measure of this objective. The EP or hospital must verify that the fields for problem list, medication list, and medication allergy list are not blank and include the most recent information known by the EP or hospital as of the time of generating the summary of care document.

For summary of care documents at transitions of care, we encourage providers to send a list of items that he or she believes to be pertinent and relevant to the patient's care, rather than a list of all problems, whether active or resolved, that have ever populated the problem list. While a current problem list must always be included, the provider can use his or her judgment in deciding which items historically present on the problem list, medical history list (if it exists in CEHRT), or surgical history list are relevant given the clinical circumstances.

Similarly, for Stage 3 we have received comments from stakeholders and through public forums and correspondence on the potential of allowing only clinically relevant laboratory test results and clinical notes (rather than all laboratory tests results and clinical notes) in the summary of care document for purposes of meeting the objective. We believe that while there may be a benefit and efficiency to be gained in the potential to limit laboratory test results or clinical notes to those most relevant for a patient's care; a single definition of clinical relevance may not be appropriate for all providers, all settings, or all individual patient diagnosis. Furthermore, we note that should a reasonable limitation around a concept of ''clinical relevance'' be added; a provider must still have the CEHRT functionality to include and send all labs or clinical notes. Therefore, we defer to provider discretion on the circumstances and cases wherein a limitation around clinical relevance may be beneficial and note that such a limitation would be incumbent on the provider to define and develop in partnership with their health IT developer as best fits their organizational needs and patient population. We specify that while the provider has the discretion to define the relevant clinical notes or relevant laboratory results to send as part of the summary of care record, providers must be able to provide all clinical notes or laboratory results through an electronic transmission of a summary of care document if that level of detail is subsequently requested by a provider receiving a transition of care or referral or the patient is transitioning to another setting of care. We note that this proposal would apply for lab results,

clinical notes, problem lists, and the care plan within the summary of care document.

For the second measure, we are proposing to address the other end of the transition of care continuum. In the Stage 2 rule, we limited the action required by providers to sending an electronic transmission of a summary of care document. We did not have a related requirement for the recipient of that transmission. We did not adopt a certification requirement for the receiving end of a transition or referral or for the measure related to sending the summary, as that is a factor outside the sending provider's immediate control. However, in Stage 3 of meaningful use, we are proposing a measure for the provider as the recipient of a transition or referral requiring them to actively seek to incorporate an electronic summary of care document into the patient record when a patient is referred to them or otherwise transferred into their care. This proposal is designed to complete the electronic transmission loop and support providers in using CEHRT to support the multiple roles a provider plays in meaningful health information exchange.

For the purposes of defining the cases in the denominator, we are proposing that what constitutes ''unavailable'' and therefore, may be excluded from the denominator, will be that a provider—

- Requested an electronic summary of care record to be sent and did not receive an electronic summary of care document; and
- Queried at least one external source via HIE functionality and did not locate a summary of care for the patient, or the provider does not have access to HIE functionality to support such a query.

We seek comment on whether electronic alerts received by EPs from hospitals when a patient is admitted, seen in the emergency room or discharged from the hospital—so called ''utilization alerts''—should be included in measure two, or as a separate measure. Use of this form of health information exchange is increasingly rapidly, driven by hospital and EP efforts to improve care transitions and reduce readmissions. We also seek comment on which information from a utilization alert would typically be incorporated into a patient's record and how this is done today.

For both the first and second measures, we are proposing that a provider may use a wide range of health IT system for health information exchange to receive or send an electronic summary of care document, but must use their certified EHR technology to create the summary of care document sent or to incorporate the summary of care document received into the patient record. We are also proposing that the receipt of the summary of care document (CCDA) may be passive (provider is sent the CCDA and incorporates it) or active (provider requests a direct transfer of the CCDA or provider queries an HIE for the CCDA). In the Stage 2 proposed rule, we noted the benefits of requiring standards for the transport mechanism for health information exchange consistently nationwide (77 FR 13723). We requested public comment in that proposed rule on the Nationwide Health Information Network specifications and a governance mechanism for health information exchange to be established by ONC. In the final rule, a governance mechanism option was included in the second measure for the Stage 2 summary of care objective at 77 FR 54020. In this Stage 3 proposed rule, we again seek comment on a health information exchange governance mechanism. Specifically we seek comment on whether providers who create a summary of care record using CEHRT for purposes of Measure 1 should be permitted to send the created summary of care record either—(1) through any electronic means; or (2) in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network. We additionally seek comment on whether providers who are receiving a summary of care record using CEHRT for the purposes of Measure 2 should have a similar requirement for the transport of summary of care documents requested from a transitioning provider. Finally, we seek comment on how a governance mechanism established by ONC at a later date could be incorporated into the EHR Incentive Programs for purposes of encouraging interoperable exchange that benefits patients and providers, including how the governance mechanism should be captured in the numerator, denominator, and thresholds for both the first (send) and second (receive) measures of this Health Information exchange objective.

For the third measure, we are proposing a measure of clinical information reconciliation which incorporates the Stage 2 objective for medication reconciliation and expands the options to allow for the reconciliation of other clinical information such as medication allergies, and problems which will allow providers additional flexibility in meeting the measure in a way that is relevant to their scope of practice. In the Stage 2 final rule, we outlined the benefits of medication reconciliation, which enables providers to validate that the patient's list of active medications is accurate (77 FR 54011 through 54012). This activity improves patient safety, improves care quality, and improves the validity of information that the provider shares with others through health information exchange. We believe that reconciliation of medication allergies and problems affords similar benefits.

For this proposed measure, we specify that the EP, eligible hospital, or CAH that receives the patient into their care should conduct the clinical information reconciliation. It is for the receiving provider that up-to-date information will be most crucial to make informed clinical judgments for patient care. We reiterate that this measure does not dictate what subset of information must be included in reconciliation. Information included in the process is determined by the provider's clinical judgment of what is most relevant to patient care.

For this measure, we propose to define clinical information reconciliation as the process of creating the most accurate patient-specific information in one or more of the specified categories by using the clinical information reconciliation capability of their certified EHR technology which will compare the ''local'' information to external/incoming information that is being incorporated into the certified EHR technology from any external source. We refer providers to the standards and certification criteria for clinical information reconciliation proposed in ONC's 2015 Edition proposed rule published elsewhere in this issue of the **Federal Register**.

As with medication reconciliation, we believe that an electronic exchange of information following the transition of care of a patient is the most efficient method of performing clinical information reconciliation.

We recognize that workflows to reconcile clinical information vary widely across providers and settings of care, and we request comment on the challenges that this objective might present for providers, and how such challenges might be mitigated, while preserving the policy intent of the measure. In particular, we solicit comment on the following:

- Automation and Manual Reconciliation. The Stage 2 measure does not specify whether reconciliation must be automated or manual. Some providers have expressed concern over the automatic inclusion of data in the patient record from referring providers, while others have indicated that

requiring manual reconciliation imposes significant workflow burden. We also seek comment on whether the use and display of meta-tagged data could address concerns related to the origin of data and thereby permit more automated reconciliation of these data elements.

- Review of Reconciled Information. Depending on clinical setting, this measure could be accomplished through manual reconciliation or through automated functionality. In either scenario, should the reconciliation or review of automated functionality be performed only by the same staff allowed under the Stage 3 requirements for the Computerized Provider Order Entry objective?
- What impact would the requirement of clinical information reconciliation have on workflow for specialists? Are there particular specialties where this measure would be difficult to meet?
- What additional exclusions, if any, should be considered for this measure?

We also encourage comment on the proposal to require reconciliation of all three clinical information reconciliation data sets, or if we should potentially require providers to choose 2 of 3 information reconciliation data sets relevant to their specialty or patient population. We expect that most providers would find that conducting clinical information reconciliation for medications, medication allergies, and problem lists is relevant for every patient encountered. We solicit examples describing challenges and burdens that providers who deliver specialist care or employ unique clinical workflow practices may experience in completing clinical information reconciliation for all three data sets and whether an exclusion should be considered for providers for whom such reconciliation may not be relevant to their scope of practice or patient population. Additionally, we solicit comments around the necessity to conduct different types of clinical information reconciliation of data for each individual patient. For example, it is possible that the data for certain patients should always be reviewed for medication allergy reconciliation, when it may not be as relevant to other patient populations.

We propose that to meet this objective, a provider must attest to the numerator and denominator for all three measures but would only be required to successfully meet the threshold for two of the three proposed measures. We invite public comment on this proposal.

Measure 1: To calculate the percentage of the first measure, CMS and ONC have worked together to define the following for this measure:

Denominator: Number of transitions of care and referrals during the EHR reporting period for which the EP or eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) was the transferring or referring provider.

Numerator: The number of transitions of care and referrals in the denominator where a summary of care record was created using certified EHR technology and exchanged electronically.

Threshold: The percentage must be more than 50 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: An EP neither transfers a patient to another setting nor refers a patient to another provider during the EHR reporting period.

* Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the measures.

Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Measure 2: To calculate the percentage of the second measure, CMS and ONC have worked together to define the following for this measure:

Denominator: Number of patient encounters during the EHR reporting period for which an EP, eligible hospital, or CAH was the receiving party of a transition or referral or has never before encountered the patient and for which an electronic summary of care record is available.

Numerator: Number of patient encounters in the denominator where an electronic summary of care record received is incorporated by the provider into the certified EHR technology.

Threshold: The percentage must be more than 40 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP, eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period is excluded from this measure.

Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the measures.

Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Measure 3: To calculate the percentage, CMS and ONC have worked together to define the following for this measure:

Denominator: Number of transitions of care or referrals during the EHR reporting period for which the EP or eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) was the recipient of the transition or referral or has never before encountered the patient.

Numerator: The number of transitions of care or referrals in the denominator where the following three clinical information reconciliations were performed: medication list, medication allergy list, and current problem list.

Threshold: The resulting percentage must be more than 80 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP, eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period is excluded from this measure.

Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the measure.

Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

We welcome comment on these proposals.

Objective 8: Public Health and Clinical Data Registry Reporting

This objective builds on the requirements set forth in the Stage 2 final rule (77 FR 54021 through 54026). In addition, this objective includes improvements to the Stage 2 measures, supports innovation that has occurred since the Stage 2 rule was released, and adds flexibility in the options that an eligible provider has to successfully report.

Further, this objective places increased focus on the importance of the ongoing lines of communication that should exist between providers and public health agencies (PHAs) or as further discussed later in this section, between providers and clinical data registries (CDRs). Providers' use of certified EHR technology can increase the flow of secure health information and reduce the burden that otherwise could attach to these important communications. The purpose of this Stage 3 objective is to further advance communication between providers and PHAs or CDRs, as well as strengthen the capture and transmission of such health information within the care continuum.

In this Stage 3 proposed rule, we are proposing changes to the Stage 1 and Stage 2 public health and specialty registry objectives to consolidate the prior objectives and measures into a single objective in alignment with efforts to streamline the program and support flexibility for providers. We propose to include a new measure for case reporting to reflect the diverse ways that providers can electronically exchange data with PHAs and CDRs. In addition, we are using new terms such as public health registries and clinical data registries to incorporate the Stage 2 designations for cancer registries and specialized registries under these categories which are used in the health care industry to designate a broader range of registry types. We further explain the use of these terms within the specifications outlined for each applicable measure.

Proposed Objective: The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

For Stage 3, we are proposing to remove the prior ''ongoing submission'' requirement and replace it with an ''active engagement'' requirement. Depending on the measure, the ongoing submission requirement from the Stage 1 and Stage 2 final rules required the successful ongoing submission of applicable data from certified EHR technology to a PHA or CDR for the entire EHR reporting period. As part of the Stage 2 final rule, we provided examples demonstrating how ongoing submission could satisfy the measure (77 FR 54021). However, stakeholders noted that the ongoing submission requirement does not accurately capture the nature of communication between providers and a PHA or CDR, and does not consider the many steps necessary to arrange for registry submission to a PHA or CDR. Given this feedback, we believe that ''active engagement'' as defined later in this section is more aligned with the process providers undertake to report to a CDR or to a PHA.

For purposes of meeting this new objective, EPs, eligible hospitals and CAHs would be required to demonstrate that ''active engagement'' with a PHA or CDR has occurred. Active engagement means that the provider is in the process of moving towards sending ''production data'' to a PHA or CDR, or— is sending production data to a PHA or CDR. We note that the term ''production data'' refers to data generated through clinical processes involving patient care, and it is here used to distinguish between this data and ''test data'' which may be submitted for the purposes of enrolling in and testing electronic data transfers. We propose that ''active engagement'' may be demonstrated by any of the following options:

Active Engagement Option 1—Completed Registration to Submit Data: The EP, eligible hospital, or CAH registered to submit data with the PHA or, where applicable, the CDR to which the information is being submitted; registration was completed within 60 days after the start of the EHR reporting period; and the EP, eligible hospital, or CAH is awaiting an invitation from the PHA or CDR to begin testing and validation. This option allows providers to meet the measure when the PHA or the CDR has limited resources to initiate the testing and validation process. Providers that have registered in previous years do not need to submit an additional registration to meet this requirement for each EHR reporting period.

Active Engagement Option 2—Testing and Validation: The EP, eligible hospital, or CAH is in the process of testing and validation of the electronic submission of data. Providers must respond to requests from the PHA or, where applicable, the CDR within 30 days; failure to respond twice within an EHR reporting period would result in that provider not meeting the measure.

Active Engagement Option 3—Production: The EP, eligible hospital, or CAH has completed testing and validation of the electronic submission and is electronically submitting production data to the PHA or CDR.

We also propose to provide support to providers seeking to meet the requirements of this objective by creating a centralized repository of national, state, and local PHA and CDR readiness. In the Stage 2 final rule (77 FR 54021), we noted the benefits of developing a centralized repository where a PHA could post readiness updates regarding their ability to accept electronic data using specifications prescribed by ONC for the public health objectives. We also published, pursuant to the Paperwork Reduction Act of 1995, a notice in the **Federal Register** on February 7, 2014 soliciting public comment on the proposed information collection required to develop the centralized repository on public health readiness (79 FR 7461). We considered the comments and we now propose moving forward with the development of the centralized repository. The centralized repository is integral to meaningful use and is expected to be available by the start of CY 2017. We expect that the centralized repository will include readiness updates for PHAs and CDRs at the state, local, and national level. We welcome your comments on the use and structure of the centralized repository.

Proposed Measures: We are proposing a total of six possible measures for this objective. EPs would be required to choose from measures 1 through 5, and would be required to successfully attest to any combination of three measures. Eligible hospitals and CAHs would be required to choose from measures one through six, and would be required to successfully attest to any combination of four measures. The measures are as shown in Table 5. As noted, measures four and five for Public Health Registry Reporting and Clinical Data Registry Reporting may be counted more than once if more than one Public Health Registry or Clinical Data Registry is available.

TABLE 5—MEASURES FOR OBJECTIVE 8: PUBLIC HEALTH AND CLINICAL DATA REGISTRY REPORTING OBJECTIVE

Measure	Maximum times measure can count towards objective for EP	Maximum times measure can count towards objective for eligible hospital or CAH
Measure 1—Immunization Registry Reporting	1	1
Measure 2—Syndromic Surveillance Reporting	1	1
Measure 3—Case Reporting	1	1
Measure 4—Public Health Registry Reporting*	3	4
Measure 5—Clinical Data Registry Reporting**	3	4
Measure 6—Electronic Reportable Laboratory Results	N/A	1

* EPs, eligible hospitals, and CAHs may choose to report to more than one public health registry to meet the number of measures required to meet the objective.

** EPs, eligible hospitals, and CAHs may choose to report to more than one clinical data registry to meet the number of measures required to meet the objective.

For EPs, we propose that an exclusion for a measure does not count toward the total of three measures. Instead, in order to meet this objective, an EP would need to meet three of the total number of measures available to them. If the EP qualifies for multiple exclusions and the remaining number of measures available to the EP is less than three, the EP can meet the objective by meeting all of the remaining measures available to them and claiming the applicable exclusions. Available measures include ones for which the EP does not qualify for an exclusion.

For eligible hospitals and CAHs, we propose that an exclusion for a measure does not count toward the total of four measures. Instead, in order to meet this objective an eligible hospital or CAH would need to meet four of the total number of measures available to them. If the eligible hospital or CAH qualifies for multiple exclusions and the total number of remaining measures available to the eligible hospital or CAH is less than four, the eligible hospital or CAH can meet the objective by meeting all of the remaining measures available to them and claiming the applicable exclusions. Available measures include ones for which the eligible hospital or CAH does not qualify for an exclusion.

We note that we are proposing to allow EPs, eligible hospitals, and CAHs to choose to report to more than one public health registry to meet the number of measures required to meet the objective. We are also proposing to allow EPs, eligible hospitals, and CAHs to choose to report to more than one clinical data registry to meet the number of measures required to meet the objective. We believe that this flexibility allows for EPs, eligible hospitals, and CAHs to choose reporting options that align with their practice and that will aid the provider's ability to care for their patients.

Measure 1—Immunization Registry Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

We believe the immunization registry reporting measure remains a priority for Stage 3 because the exchange of information between certified EHR technology and immunization registries allows a provider to use the most complete immunization history available to inform decisions about the vaccines a patient may need. Public health agencies and providers also use immunization information for emergency preparedness and to estimate population immunization coverage levels of certain vaccines.

We propose that to successfully meet the requirements of this measure, bidirectional data exchange between the provider's certified EHR technology and the immunization registry/IIS is required. We understand that many states and local public health jurisdictions are exchanging immunization data bidirectionally with providers, and that the number of states and localities able to support bidirectional exchange continues to increase. In the 2015 Edition proposed rule published by ONC elsewhere in this issue of the **Federal Register**, the ONC is proposing to adopt a bidirectional exchange standard for reporting to immunization registries/IIS. We believe this functionality is important for patient safety and improved care because it allows the provider to use the most complete immunization record possible to make decisions on whether a patient needs a vaccine. Immunization registries and health IT systems also are able to provide immunization forecasting functions which can inform discussions between providers and patients on what vaccines they may need in the future and the timeline for the receipt of such immunizations. Therefore, we believe that patients, providers, and the public health community would benefit from technology that can accommodate bidirectional immunization data exchange. We welcome comment on this proposal.

Exclusion for Measure 1: Any EP, eligible hospital, or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure if the EP, eligible hospital, or CAH: (1) Does not administer any immunizations to any of the populations for which data is collected by their jurisdiction's immunization registry or immunization information system during the EHR reporting period; (2) operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data at the start of the EHR reporting period.

Measure 2—Syndromic Surveillance Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care ambulatory setting for EPs, or an emergency or urgent care department for eligible hospitals and CAHs (POS 23). This measure remains a policy priority for Stage 3 because electronic syndromic surveillance is valuable for early detection of outbreaks, as well as monitoring disease and condition trends. We are

distinguishing between EPs and eligible hospital or CAHs reporting locations because, as discussed in the Stage 2 final rule, few PHAs appeared to have the ability to accept non-emergency or non-urgent care ambulatory syndromic surveillance data electronically (77 FR 53979). We continue to observe differences in the infrastructure and current environments for supporting electronic syndromic surveillance data submission to PHAs between eligible hospitals or CAHs and EPs. Because eligible hospitals and CAHs send syndromic surveillance data using different methods as compared to EPs, we are defining slightly different exclusions for each setting as described later in this section.

Exclusion for EPs for Measure 2: Any EP meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the EP: (1) Does not treat or diagnose or directly treat any disease or condition associated with a syndromic surveillance system in their jurisdiction; (2) operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from EPs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from EPs at the start of the EHR reporting period.

Exclusion for eligible hospitals/CAHs for Measure 2: Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the eligible hospital or CAH: (1) Does not have an emergency or urgent care department; (2) operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from eligible hospitals or CAHs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs at the start of the EHR reporting period.

Measure 3—Case Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.

This is a new reporting option that was not part of Stage 2. The collection of electronic case reporting data greatly improves reporting efficiencies between providers and the PHA. Public health agencies collect ''reportable conditions'', as defined by the state, territorial, and local PHAs to monitor disease trends and support the management of outbreaks. In many circumstances, there has been low reporting compliance because providers do not know when, where, or how to report. In some cases, the time burden to report can also contribute to low reporting compliance. However, electronic case reporting presents a core benefit to public health improvement and a variety of stakeholders have identified electronic case reporting as a high value element of patient and continuity of care. Further, we believe that electronic case reporting reduces burdensome paper-based and labor-intensive case reporting. Electronic reporting will support more rapid exchange of case reporting information between PHAs and providers and can include structured questions or data fields to prompt the provider to supply additional required or care-relevant information.

To support case reporting, the ONC has proposed a certification criterion that includes capabilities to enable certified EHR systems to send initial case reporting data and receive a request from the public health agency for supplemental or ad hoc structured data in the 2015 Edition proposed rule, published elsewhere in this issue of the **Federal Register**.

Exclusion for Measure 3: Any EP, eligible hospital, or CAH meeting one or more of the following criteria may be excluded from the case reporting measure if the EP, eligible hospital, or CAH: (1) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period; (2) operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data at the start of the EHR reporting period.

Measure 4—Public Health Registry Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit data to public health registries.

In the Stage 2 final rule, we were purposefully general in our use of the term ''specialized registry'' (other than a cancer registry) to encompass both registry reporting to public health agencies and clinical data registries in order to prevent inadvertent exclusion of certain registries through an attempt to be more specific (77 FR 54030). In response to insight gained from the industry through listening sessions, public forums, and reponses to the February 2014 Public Health Reporting RFI; we propose to carry forward the concept behind this broad category from Stage 2, but also propose to split public health registry reporting from clinical data registry reporting into two separate measures which better define the potential types of registries available for reporting. We propose to define a ''public health registry'' as a registry that is administered by, or on behalf of, a local, state, territorial, or national PHA and which collects data for public health purposes. While immunization registries are a type of public health registry, we propose to keep immunization registry reporting separate from the public health registry reporting measure to retain continuity from Stage 1 and 2 policy in which immunization registry reporting was a distinct and separate objective (77 FR 54023). We believe it is important to retain the public health registry reporting option for Stage 3 because these registries allow the public health community to monitor health and disease trends, and inform the development of programs and policy for population and community health improvement.

We reiterate that any EP, eligible hospital, or CAH may report to more than one public health registry to meet the total number of required measures for the objective. For example, if a provider meets this measure through reporting to both the National Hospital Care Survey and the National Healthcare Safety Network registry, the provider could get credit for meeting two measures. ONC will consider the adoption of standards and implementation guides in future rulemaking. Should these subsequently be finalized, they may then be adopted as part of the certified EHR technology definition as it relates to meeting the public health registry reporting measure through future rulemaking for the EHR Incentive Programs.

We further note that ONC adopted standards for ambulatory cancer case reporting in its final rule ''2014 Edition, Release 2 EHR Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange'' (79 FR 54468) and we provided EPs the option to select the cancer case reporting menu objective in the Stage 2 final rule (77 FR 54029 through 54030). We included cancer registry reporting as a separate objective from specialized registry reporting

because it was more mature in its development than other registry types, not because other reporting was intended to be excluded from meaningful use. For the Stage 3 public health registry reporting measure, given the desire to provide more flexible options for providers to report to the registries most applicable for their scope of practice, we propose that EPs would have the option of counting cancer case reporting under the public health registry reporting measure. We note that cancer case reporting is not an option for eligible hospitals and CAHs under this measure because hospitals have traditionally diagnosed or treated cancers and have the infrastructure needed to report cancer cases.

Exclusions for Measure 4: Any EP, eligible hospital, or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure if the EP, eligible hospital, or CAH: (1) Does not diagnose or directly treat any disease or condition associated with a public health registry in their jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

Measure 5—Clinical Data Registry Reporting: The EP, eligible hospital, or CAH is in active engagement to submit data to a clinical data registry.

As discussed in the Public Health Registry Reporting measure, we propose to split specialized registry reporting into two separate, clearly defined measures: Public health registry reporting and clinical data registry reporting. In Stage 2 for EPs, reporting to specialized registries is a menu objective and this menu objective includes reporting to clinical data registries. For Stage 3, we propose to include clinical data registry reporting as an independent measure. The National Quality Registry Network defines clinical data registries as those that record information about the health status of patients and the health care they receive over varying periods of time.[12] We propose to further differentiate between clinical data registries and public health registries as follows: For the purposes of meaningful use, ''public health registries'' are those administered by, or on behalf of, a local, state, territorial, or national public health agencies; and ''clinical data registries'' are administered by, or on behalf of, other non-public health agency entities. We believe that clinical data registries are important for providing information that can inform patients and their providers on the best course of treatment and for care improvements, and can support specialty reporting by developing reporting for areas not usually covered by PHAs but that are important to a specialist's provision of care. Clinical data registries can also be used to monitor health care quality and resource use.

As noted previously, we reiterate that any EP, eligible hospital, or CAH may report to more than one clinical data registry to meet the total number of required measures for this objective. ONC will consider the adoption of standards and implementation guides in future rulemaking. Should these subsequently be finalized, they may then be adopted as part of the certified EHR technology definition as it relates to meeting the clinical data registry reporting measure through future rulemaking for the EHR Incentive Programs.

Exclusions for Measure 5: Any EP, eligible hospital, or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure if the EP, eligible hospital, or CAH: (1) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no clinical data registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

Measure 6—Electronic Reportable Laboratory Result Reporting: The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results. This measure is available to eligible hospitals and CAHs only. Electronic reportable laboratory result reporting to PHAs is required for eligible hospitals and CAHs in Stage 2 (77 FR 54021). We propose to retain this measure for Stage 3 to promote the exchange of laboratory results between eligible hospitals/CAHs and PHAs for improved timeliness, reduction of manual data entry errors, and more complete information.

Exclusion for Measure 6: Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result reporting measure if the eligible hospital or CAH: (1) Does not perform or order laboratory tests that are reportable in their jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no public health agency is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results from an eligible hospital or CAH at the start of the EHR reporting period.

The Use of CEHRT for the Public Health and Clinical Data Registry Reporting Objective

As proposed previously, the Public Health and Clinical Data Registry Reporting objective requires active engagement with a public health agency to submit electronic public health data from certified EHR technology. ONC defined the standards and certification criteria to meet the definition of CEHRT in its 2011, 2014, and 2014 Release 2 Edition EHR certification criteria rules (see section II.B. of the ''2014 Edition, Release 2 EHR Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange'' for a full description of ONC's regulatory history; (79 FR 54434)). For example, ONC adopted standards for immunization reporting (see § 170.314(f)(1) and (f)(2)), inpatient syndromic surveillance (see § 170.314(f)(3) and (f)(7)), ELR (see § 170.314(f)(4)), and cancer case reporting (see § 170.314(f)(5) and (f)(6)) in its 2014 Edition final rule.

We support ONC's intent to promote standardized and interoperable exchange of public health data across the country. Therefore, to meet all of the measures within this public health objective EPs, eligible hospitals, and CAHs must use CEHRT as we propose to define it under § 495.4 in this proposed rule and use the standards included in the 2015 Edition proposed rule published elsewhere in this edition of the **Federal Register**. We anticipate that as new public health registries and clinical data registries are created, ONC and CMS will work with the public health community and clinical specialty societies to develop ONC-certified

[12] *https://download.ama-assn.org/resources/doc/cqi/x-pub/nqrn-what-is-clinical-data-registry.pdf.*

electronic reporting standards for those registries so that providers have the option to count participation in those registries under the measures of this objective. ONC will look to adopt such standards, as appropriate, in future rules published by ONC.

We welcome public comment on these proposals.

II. Provisions of the Proposed Regulations

A. Meaningful Use Requirements, Objectives and Measures

2. Certified EHR Technology (CEHRT) Requirements

Certified EHR technology is defined for the Medicare and Medicaid EHR Incentive Programs at 42 CFR 495.4, which references ONC's definition of CEHRT under 45 CFR 170.102. The definition establishes the requirements for EHR technology that must be used by providers to meet the meaningful use objectives and measures. The Stage 2 final rule requires that CEHRT must be used by EPs, eligible hospitals, and CAHs to satisfy their CQM reporting requirements under the Medicare and Medicaid EHR Incentive Programs. In addition, the CQM data reported to CMS must originate from EHR technology that is certified to ''capture and export'' in accordance with 45 CFR 170.314(c)(1) and ''electronic submission'' in accordance with 45 CFR 170.314(c)(3) (77 FR 54053).

On September 4, 2014, CMS and ONC published a final rule in the **Federal Register** (79 FR 52910 through 52933) that, among other things, modified the meaningful use requirements for 2014 and the CEHRT definition.

First, we granted flexibility to providers who experienced product availability issues that affected their ability to fully implement EHR technology certified to the 2014 Edition of certification criteria (79 FR 52913 through 52926). We allowed those EPs, eligible hospitals, and CAHs to continue using either EHR technology certified to the 2011 Edition, or a combination of EHR technology certified to the 2011 Edition and 2014 Edition, for the EHR reporting periods in CY 2014 and FY 2014. EPs, eligible hospitals, and CAHs could take one of these approaches if they were unable to fully implement EHR technology certified to the 2014 Edition for an EHR reporting period in 2014 due to delays in the availability of EHR technology certified to the 2014 Edition.

Second, we established that in order to receive an incentive payment for 2014 under Medicaid for adopting, implementing, or upgrading CEHRT, a provider must adopt, implement, or upgrade to EHR technology certified to the 2014 Edition and meet the CEHRT definition (79 FR 52925 through 52926).

Finally, ONC revised the CEHRT definition under 45 CFR 170.102 to align with our policy allowing for the use of EHR technology certified to the 2011 Edition, or a combination of EHR technology certified to the 2011 Edition and 2014 Edition, in 2014 (79 FR 52930).

For further detail on the changes to the requirements for 2014 and CEHRT definition, we refer readers to the 2014 CEHRT Flexibility final rule (79 FR 52910 through 52933).

a. CEHRT Definition for the EHR Incentive Programs

As we have stated previously in rulemaking, the statute and regulations require EPs, eligible hospitals, and CAHs to use ''Certified EHR Technology'' if they are to be considered meaningful EHR users and eligible for incentive payments under Medicare or Medicaid, and to avoid payment adjustments under Medicare (for example, see section 1848(o)(2)(A)(i) of the Act, and 42 CFR 495.4). However, in contrast to prior rulemaking cycles where ONC has established a meaningful-use-specific CEHRT definition for the EHR Incentive Programs that CMS has adopted by cross-reference under 42 CFR 495.4, we propose to take a different approach under which we would define the term ''Certified EHR Technology,'' and that definition would be specific to the EHR Incentive Programs.

This proposed change is designed to simplify the overall regulatory relationship between ONC and CMS rules for stakeholders and to ensure that relevant CMS policy for the EHR Incentive Programs is clearly referenced in CMS regulations. For example, ONC's definition of CEHRT under 45 CFR 170.102 includes the compliance dates for EPs, eligible hospitals, and CAHs to use EHR technology certified to a particular edition of certification criteria to meet the CEHRT definition and for purposes of the EHR Incentive Programs, such as the requirement to use EHR technology certified to the 2014 Edition beginning in 2015. Under the proposed new approach, we would establish through rulemaking for the EHR Incentive Programs (either with stand-alone rulemaking or through other vehicles such as the annual Medicare payment rules) the compliance dates by which providers must use EHR technology certified to a particular edition of certification criteria to meet the CEHRT definition, which would be reflected in our regulations under 42 CFR part 495 rather than ONC's regulations under 45 CFR part 170.

b. Defining CEHRT for 2015 Through 2017 and for 2018 and Subsequent Years

In adopting a CEHRT definition specific for the EHR Incentive Programs, we propose to include, as currently for the ONC CEHRT definition under 45 CFR 170.102, the relevant Base EHR definitions adopted by ONC in 45 CFR 170.102 and other ONC certification criteria relevant to the EHR Incentive Programs. We refer readers to ONC's 2015 Edition proposed rule published elsewhere in this issue of the **Federal Register** for the proposed 2015 Edition Base EHR definition and discussion of the 2014 Edition Base EHR definition. We are including the Base EHR definition(s) because as ONC explained in the 2014 Edition final rule ''2014 Edition, Release 2 EHR Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange'' (77 FR 54443 through 54444) the ''Base EHR'' essentially serves as a substitute for the term ''Qualified EHR'' in the definition of CEHRT. The term ''Qualified EHR'' is defined in section 3000(13) of the PHSA, to include certain capabilities listed in that section, and is included in the statutory definition of ''certified EHR technology'' for the EHR Incentive Programs (for example, see section 1848(o)(4) of the Act). The Base EHR definition(s) also include additional capabilities as proposed by ONC that we agree all providers should have that are participating in the EHR Incentive Programs to support their attempts to meet meaningful use objectives and measures as well as interoperable health information exchange.

We propose to define the editions of certification criteria that may be used for years 2015 through 2017 to meet the CEHRT definition. At a minimum, EPs, eligible hospitals, and CAHs would be required to use EHR technology certified to the 2014 Edition certification criteria for their respective EHR reporting periods in 2015 through 2017. A provider may also upgrade to the 2015 Edition prior to 2018 to meet the required certified EHR technology definition for the EHR reporting periods in 2015, 2016, or 2017, or they may use a combination of 2014 and 2015 Editions prior to 2018 if they have modules from both Editions which meet the requirements for the objectives and measures or if they fully upgrade during an EHR reporting period.

Based on experience with delays in the availability of EHR technology certified to the 2014 Edition for providers to implement and use to meet meaningful use for an EHR reporting period in 2014, we propose to include as part of the CEHRT definition a longer period of time for providers to use technology certified to the 2014 Edition in an effort to give providers more time in updating their technology to the 2015 Edition before the EHR reporting period in 2018. We also propose to make the use of a combination of technology certified to the 2014 Edition and 2015 Edition to meet the CEHRT definition more flexible in 2015 through 2017 by taking into account ONC's proposed new privacy and security certification approach for health IT (see ONC's 2015 Edition proposed rule published elsewhere in this issue of the **Federal Register**). Specifically, as a provider updates to technology certified to the 2015 Edition, the provider would not necessarily need to continue to meet the privacy and security capability requirements of the 2014 Edition Base EHR definition because the technology they adopt certified to the 2015 Edition would include necessary privacy and security capabilities. Additionally, because ONC is proposing, for the 2015 Edition, to no longer require certification of Health IT Modules to capabilities that support meaningful use objectives with percentage-based measures, we propose to include these capabilities (45 CFR 170.314(g)(1) or (2) or 45 CFR 170.315(g)(1) or (2)), as applicable, in the CEHRT definition for 2015 through 2017 so that providers have technology that can appropriately record and calculate meaningful use measures. We note that there are many combinations of 2014 and 2015 Edition certified technologies that could be used to successfully meet the transitions of care requirements included in the 2014 and 2015 Edition Base EHR definitions for the purposes of meeting meaningful use objectives and measures. We believe we have identified all combinations in the proposed regulation text under § 495.4 that could be used to meet the CEHRT definition through 2017 and be used for the purposes of meeting meaningful use objectives and measures. We welcome comments on the accuracy of the identified available options.

We propose that starting with 2018, all EPs, eligible hospitals, and CAHs would be required to use technology certified to the 2015 Edition to meet the CEHRT definition and demonstrate meaningful use for an EHR reporting period in 2018 and subsequent years. The CEHRT definition would include, for the reasons discussed previously, meeting the 2015 Edition Base EHR definition and having other important capabilities, that include the capabilities to—

- Record or create and incorporate family health history;
- Capture patient health information such as advance directives;
- Record numerators and denominators for meaningful use objectives with percentage-based measures and calculate the percentages;
- Calculate and report clinical quality measures; and
- Any other capabilities needed to be a Meaningful EHR User.

For information on 2015 Edition certification criteria that include these capabilities and are associated with proposed Meaningful Use objectives for Stage 3, please see the 2015 Edition proposed rule published elsewhere in this issue of the **Federal Register**. We expect that the certification criteria with capabilities that support CQM calculation and reporting would be jointly proposed with CQM reporting requirements in a separate rulemaking.

c. Proposed Definition for CEHRT

For the reasons stated previously, we propose to adopt a definition of Certified EHR Technology under 42 CFR 495.4 for the Medicare and Medicaid EHR Incentive Programs that would apply for the EHR reporting periods in 2015 up to and including 2017 and for the EHR reporting periods in 2018 and subsequent years. We refer readers to ONC's 2015 Edition proposed rule published elsewhere in this issue of the **Federal Register** for further explanation of the concepts and terms used in our proposed definition of Certified EHR Technology, including the 2014 Edition Base EHR definition, 2015 Edition Base EHR definition, certification criteria, and the regulation text under 45 CFR part 170.

B. Reporting on Clinical Quality Measures Using Certified EHR Technology by EPs, Eligible Hospitals, and Critical Access Hospitals

1. Clinical Quality Measure (CQM) Requirements for Meaningful Use in 2017 and Subsequent Years

Under sections 1848(o)(2)(A), 1886(n)(3)(A), and 1814(l)(3)(A) of the Act and 42 CFR 495.4, EPs, eligible hospitals, and CAHs must report on CQMs selected by CMS using certified EHR technology, as part of being a meaningful EHR user under the Medicare and Medicaid EHR Incentive Programs.

In regard to the selection of CQMs, we expect to continue to include CQMs that align with the National Quality Strategy; as well as, the our Quality Strategy. We also expect to consider programmatic goals and outcome measures that would advance patient and population health.

a. Clinical Quality Measure Reporting Requirements for EPs

Section 1848(o)(2)(B)(iii) of the Act requires that in selecting measures for EPs for the Medicare EHR Incentive Program, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting, including reporting under subsection (k)(2)(C) for the Physician Quality Reporting System (PQRS). Consistent with that requirement, in the Stage 2 final rule, we finalized a policy to align certain aspects of reporting CQMs for the Medicare EHR Incentive Program for EPs with reporting under the PQRS. Specifically, we stated that Medicare EPs who participate in both the PQRS and the Medicare EHR Incentive Program will satisfy the CQM reporting component of meaningful use if they submit and satisfactorily report PQRS CQMs under the PQRS's EHR reporting option using CEHRT (77 FR 54058).

Section 1848(m)(7) of the Act requires the Secretary to develop a plan to integrate reporting on quality measures under the PQRS with reporting requirements under the Medicare EHR Incentive Program relating to the meaningful use of electronic health records. Therefore, it is our goal to align the reporting requirements for the CQM component of meaningful use under the Medicare EHR Incentive Program and for PQRS wherever possible. Historically, most requirements for the Medicare and Medicaid EHR Incentive Programs have been established through stand-alone rulemaking, such as the rules for Stage 1 (75 FR 44314 through 44588) and Stage 2 (77 FR 53968 through 54162), which span multiple program years. This limited our ability to align the EHR Incentive Program with the requirements established in the annual Medicare payment rules for other CMS quality programs affecting physicians and other EPs.

To further our goals of alignment and avoiding redundant or duplicative reporting across the various CMS quality reporting programs, we intend to address CQM reporting requirements for the Medicare and Medicaid EHR Incentive Program for EPs for 2017 and subsequent years in the Medicare Physician Fee Schedule (PFS) rulemaking, which also establishes the requirements for PQRS and other

quality programs affecting EPs. We note that the form and manner of reporting of CQMs for Medicare EPs would also be included in the PFS, while for Medicaid we would continue to allow the states to determine form and method requirements subject to CMS approval. We propose to continue the policy of establishing certain CQM requirements that apply for both the Medicare and Medicaid EHR Incentive Programs including a common set of CQMs and the reporting periods for CQMs in the EHR Incentive Programs. However, we believe that receiving and reviewing public comments for various CMS quality programs at one time (for example, EHR Incentive Program, PQRS, Physician Compare); and finalizing the requirements for these programs simultaneously, would allow us to better align these programs for EPs to support streamlined reporting and program efficacy. We propose to continue to support active communication with providers to facilitate the sharing of information related to CQM selection and reporting, the announcement of opportunities for public comment on CQM selection and reporting, and upcoming or relevant CQM program milestones in partnership with state Medicaid programs and the Medicare quality reporting programs. We propose to continue to post the defined CQM sets and the published electronic specifications for CQM that are in use for all aligned programs on the CMS Web site as currently posted on the eCQM Library page: *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html.*

b. CQM Reporting Requirements for Eligible Hospitals and Critical Access Hospitals

Section 1886(n)(3)(B)(iii) of the Act requires that, in selecting measures for eligible hospitals for the Medicare EHR Incentive Program, and establishing the form and manner for reporting measures, the Secretary shall seek to avoid redundant or duplicative reporting with reporting otherwise required, including reporting under section 1886(b)(3)(B)(viii) of the Act, the Hospital IQR Program.

Similar to our intentions for EPs discussed previously, and to further our alignment goal among CMS quality reporting programs for eligible hospitals and CAHs, and avoid redundant or duplicative reporting among hospital programs, we intend to address CQM reporting requirements for the Medicare and Medicaid EHR Incentive Program for eligible hospitals and CAHs for 2016, 2017, and future years, in the Inpatient Prospective Payment System (IPPS) rulemaking. IPPS rulemaking also establishes the requirements for the Hospital IQR Program and other quality programs affecting hospitals. We intend to include all Medicare EHR Incentive Program requirements related to CQM reporting in the IPPS rulemaking including, but not limited to, new program requirements, reporting requirements, reporting and submission periods, reporting methods, and information regarding the CQMs. As with EPs, for the Medicaid EHR Incentive Program we would continue to allow the states to determine form and method requirements subject to CMS approval. However, as previously noted, this proposal would continue the policy of establishing certain CQM requirements that apply for both the Medicare and Medicaid EHR Incentive Programs including a common set of CQMs and the reporting periods for CQMs in the EHR Incentive Programs. We believe that receiving and reviewing public comments for various CMS quality programs at one time and finalizing the requirements for these programs simultaneously would allow us to better align these programs for eligible hospitals and CAHs, allow more flexibility into the Medicare and Medicaid EHR Incentive Programs, and add overall value and consistency by providing us the opportunity to address public comments that affect multiple programs at one time. We propose to continue to support active communication with providers to facilitate the sharing of information related to CQM selection and reporting, the announcement of opportunities for public comment on CQM selection and reporting, and upcoming or relevant CQM program milestones in partnership with state Medicaid programs and the Medicare quality reporting programs. We propose to continue to post the defined CQM sets and the published electronic specifications for CQM that are in use for all aligned programs on the CMS Web site as currently posted on the eCQM Library page: *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html.*

2. CQM Reporting Period

In the Stage 2 final rule, we finalized a reporting period for CQMs for EPs, eligible hospitals, and CAHs (see 77 FR 54049 through 54051). In the FY 2015 IPPS final rule, we began to shift CQM reporting to a calendar year basis for eligible hospitals and CAHs for the Medicare EHR Incentive Program (79 FR 50319 through 50321). We established that for eligible hospitals and CAHs that submit CQMs electronically in 2015, the reporting period is one calendar quarter from Q1, Q2, or Q3 of CY 2015 (79 FR 50321).

As discussed in sections II.A.1.c.(1).(b).(i). and II.F. of this proposed rule, we are proposing to require an EHR reporting period of 1 full calendar year for meaningful use for providers participating in the Medicare EHR Incentive Program, with a limited exception for Medicaid providers demonstrating meaningful use for the first time. We are proposing to require the same length for the CQM reporting period for EPs, eligible hospitals, and CAHs beginning in 2017. As noted, we are proposing a limited exception for Medicaid providers demonstrating meaningful use for the first time who would have a CQM reporting period of any continuous 90 days that is the same 90-day period as their EHR Reporting Period.

We believe full year reporting would allow for the collection of more comparable data across CMS quality programs and increase alignment across those programs. The more robust data set provided by a full year reporting period offers more opportunity for alignment than the data set provided by a shorter reporting period, especially compared across years. We further believe this full calendar year reporting period for CQMs would reduce the complexity of reporting requirements for the Medicare EHR Incentive Program by streamlining the reporting timeline for providers for CQMs and meaningful use objectives and measures. We welcome comment on the following proposals.

a. CQM Reporting Period for EPs

With the previously stated considerations in mind, and in an effort to align with other CMS quality reporting programs such as the PQRS, we propose to require for CQM reporting under the EHR Incentive Program a reporting period of one full calendar year for all EPs participating in the Medicare and Medicaid EHR Incentive Program, with a limited exception for Medicaid providers demonstrating meaningful use for the first time who would have a CQM reporting period of any continuous 90 days that is the same 90-day period as their EHR Reporting Period. These reporting periods would apply beginning in CY 2017 for all EPs participating in the EHR Incentive Program.

b. CQM Reporting Period for Eligible Hospital/CAH

For eligible hospitals and CAHs in 2017 and subsequent years, we are proposing to require a reporting period of 1 full calendar year which consists of 4 quarterly data reporting periods for providers participating in the Medicare and Medicaid EHR Incentive Program, with a limited exception for Medicaid providers demonstrating meaningful use for the first time who would have a CQM reporting period of any continuous 90 days that is the same 90-day period as their EHR Reporting Period. More details of the form and manner will be provided in the IPPS rulemaking cycle.

c. Reporting Flexibility EPs, Eligible Hospitals, CAHs 2017

In order to align with the flexibility option of participation in Meaningful Use in 2017 (see section II.C.1.b. of this proposed rule), we are proposing that EPs, eligible hospitals, and CAHs would be able to have more flexibility to report CQMs in one of two ways in 2017—via electronic reporting or attestation. First EPs, eligible hospitals, and CAHs may choose to report eCQMs electronically using the CQMs finalized for use in 2017 using the most recent version of the eCQMs (electronic specifications), which would be the electronic specifications of the CQMs published by CMS in 2016. Alternately, a provider may choose to continue to attest also using the most recent (2016 version) eCQM electronic specifications. We note that the intent to allow attestation in 2017 is to provide flexibility for providers transitioning between versions of CEHRT in 2017 and believe that requiring the most recent version of the annual updates should not be a significant burden given that developers do not need to recertify a product each time CQM specifications are updated. However, we seek comment on if CMS should consider allowing providers to report using another earlier version of the specifications.

We note that, unlike the flexible options established in rulemaking in 2014 (79 FR 52927 through 52930), providers may select the CQMs they choose to report separately from the Stage objectives and measures of meaningful use for their EHR reporting period in 2017.

We invite public comment on our proposals.

3. Reporting Methods for CQMs

In the Stage 2 final rule, we finalized the reporting methods for CQMs for EPs (77 FR 54075 through 54078), eligible hospitals, and CAHs (77 FR 54087 through 54089) for the Medicare EHR Incentive Program, which included reporting electronically, where feasible, or by attestation. To further align the Medicare and Medicaid EHR Incentive Programs with programs such as PQRS and the Hospital IQR program, starting in 2017, we propose to continue to encourage electronic submission of CQM data for all EPs, eligible hospitals, and CAHs where feasible; however, as outlined in section II.C.1.b. of this proposed rule, we would allow attestation for CQMs in 2017. For 2018 and subsequent years, we are proposing that providers participating in the Medicare program must electronically report where feasible and that attestation to CQMs would no longer be an option except in certain circumstances where electronic reporting is not feasible. This would include providers facing circumstances which render them unable to electronically report (such as a data submission system failure, natural disaster, or certification issue outside the control of the provider) who may attest to CQMs if they also attest that electronically reporting was not feasible for their demonstration of meaningful use for a given year. We believe that the collection and electronic reporting of data through health information technology would greatly simplify and streamline reporting for many CMS quality reporting programs and reduce the burden of quality measure reporting for providers who participate in these programs. We also believe this would further encourage the adoption and use of certified EHR technology by allowing EPs, eligible hospitals, and CAHs to report data for multiple programs through a single electronic submission. Through electronic reporting, EPs, eligible hospitals, and CAHs would be able to leverage EHRs to capture, calculate, and electronically submit quality data to CMS for the Medicare EHR Incentive Program. We note that we intend to address the form and manner of electronic reporting in future Medicare payment rules.

For the Medicaid EHR Incentive Program, as in the Stage 2 rulemaking (77 FR 54089), we propose that states would continue in Stage 3 to be responsible for determining whether and how electronic reporting of CQMs would occur, or whether they wish to continue to allow reporting through attestation. If a state does require such electronic reporting, the state is responsible for sharing the details of the process with its provider community. We anticipate that whatever means states have deployed for capturing CQMs electronically for Stages 1 and 2 would be similar for reporting in Stage 3. However, we note that subject to our prior approval, this is within the states' purview. We propose for Stage 3 that the states would establish the method and requirements, subject to our prior approval, for the electronic capture and reporting of CQMs from CEHRT.

PROPOSED eCQM REPORTING TIMELINES FOR MEDICARE & MEDICAID EHR INCENTIVE PROGRAM

Year	2017 only	2017 only	2018 and subsequent years.	2018 and subsequent years.
Reporting Method Available.	Attestation	Electronic Reporting	Attestation	Electronic Reporting.
Provider Type who May Use Method.	All Medicare providers	All Medicare Providers	Medicare Providers with circumstances rendering them unable to eReport.	All Medicare Providers.
	Medicaid providers must refer to state requirements for reporting.	Medicaid providers must refer to state requirements for reporting.	Medicaid providers must refer to state requirements for reporting.	Medicaid providers must refer to state requirements for reporting.
CQM Reporting Period	1 CY for Medicare	1 CY for Medicare	1 CY for Medicare	1 CY for Medicare.
	1 CY for returning Medicaid.	1 CY for returning Medicaid.	1 CY for returning Medicaid.	1 CY for returning Medicaid.
	90 days for first time meaningful user Medicaid.	90 days for first time meaningful user Medicaid.	90 days for first time meaningful user Medicaid.	90 days for first time meaningful user Medicaid.

PROPOSED eCQM REPORTING TIMELINES FOR MEDICARE & MEDICAID EHR INCENTIVE PROGRAM—Continued

eCQM Version Required (CQM electronic specifications update).	2016 Annual Update	2016 Annual Update	2016 Annual Update or more recent version.	2017 Annual Update.
CEHRT Edition Required	2014 Edition Or 2015 Edition	2014 Edition Or 2015 Edition	2015 Edition	2015 Edition.

We invite public comments on our proposals.

a. Quality Reporting Data Architecture Category III (QRDA–III) Option for Eligible Hospitals and CAHs

In the Stage 2 final rule (77 FR 54088), we finalized two options for eligible hospitals and CAHs to electronically submit CQMs beginning in FY 2014 under the Medicare EHR Incentive Program. Option 1 was to submit aggregate level CQM data using QRDA–III electronically. Option 2 was to submit data electronically using a method similar to the 2012 and 2013 Medicare EHR Incentive Program electronic reporting pilot for eligible hospitals and CAHs, which used QRDA–I (patient-level data).

We noted in the FY 2014 and 2015 IPPS/LTCH PPS final rules (78 FR 50904 through 50905 and 79 FR 50321 through 50322) that we had determined that the electronic submission of aggregate-level data using QRDA–III would not be feasible in 2014 or 2015 for eligible hospitals and CAHs under the Medicare EHR Incentive Program. We stated that we would reassess this policy for future reporting periods.

In this proposed rule, we are proposing to remove the QRDA–III option for eligible hospitals and CAHs, as we have found this is not an option for electronic reporting as we move forward with the EHR Incentive Program, we believe the calculations, per the QRDA–III, are not advantageous to quality improvement. As the EHR Incentive Program further aligns with the Hospital IQR program, we intend to continue utilizing the electronic reporting standard of QRDA–I patient level data that we finalized in the FY 2015 IPPS rule (79 FR 50322), which will allow the same level of CQM reporting, and use and analysis of these data for quality improvement initiatives.

As we understand the need to support state flexibility, we are also proposing that states would continue to have the option, subject to our prior approval, to allow or require QRDA–III for CQM reporting.

4. CQM Specification and Changes to the Annual Update

In the Stage 2 final rule, we stated that we do not intend to use notice and comment rulemaking as a means to update or modify electronic CQM (eCQM) specifications (77 FR 54055). In general, it is the role of the measure steward to make changes to a CQM in terms of the initial patient population, numerator, denominator, potential exclusions, logic, and value sets. We recognize that it may be necessary to update CQM specifications after they have been published to ensure their continued clinical relevance, accuracy, and validity. CQM specification updates may include administrative changes, such as adding the NQF endorsement number to a CQM, correcting faulty logic, adding or deleting codes as well as providing additional implementation guidance for a CQM.

These changes are described through the annual updates to the electronic specifications for EHR submission published by CMS. CQMs are currently tracked on a version basis as updates are made and we require EPs, eligible hospitals, and CAHs to submit the versions of the CQMs as identified on our Web site. The Web site contains all versions of the CQMs since reporting via attestation does not require the most recent version of the CQMs, but electronic reporting of the CQMs does require the most recent version to be reported. Because we require the most recent version of the CQM specifications to be used for electronic reporting methods, we understand that EHR vendors must make CQM updates on an annual basis. We also understand that providers must regularly implement those updates to stay current with the most recent CQM version.

We continue to evaluate the CQM update timeline and look for ways to provide CQM updates timely, so that vendors can develop, test, and deploy these updates and providers can implement those updates as necessary. We have the flexibility to update CQMs so they remain clinically relevant, accurate, and valid. While we are not proposing any change to our policy on updating CQM specifications in this proposed rule, we seek comment on our annual update timeline and suggestions for how to improve the CQM update process.

5. EHR Technology Certification Requirements for Reporting of CQMs

In the 2014 Edition EHR Certification Criteria Final Rule, ONC finalized certain certification criteria to support the MU objectives and CQMs set forth by CMS. In that rule, ONC also specified that in order for an EP, eligible hospital, or CAH to have EHR technology that meets the Base EHR definition, the EHR technology must be certified to a minimum of nine CQMs for EPs or 16 CQMs for eligible hospitals and CAHs (77 FR 54264 through 54265; see also 45 CFR 170.102). This is the same number required for quality reporting to the Medicare and Medicaid EHR Incentive Programs, the PQRS EHR reporting and, beginning in 2015, the electronic reporting option under the Hospital IQR Program. In certain cases, an EP, eligible hospital or CAH may purchase an EHR product that is certified to the minimum number of CQMs and discover that, for at least one of those CQMs, they do not have data on which to report. In these cases, the EP (77 FR 54058 through 54059), eligible hospital or CAH (77 FR 54051) would report a zero denominator for one or more CQMs.

We believe EHRs should be certified to more than the minimum number of CQMs required by one or more CMS quality reporting programs so that EPs, eligible hospitals, and CAHs have a choice of which CQMs to report, and could therefore choose to report on CQMs most applicable to their patient population or scope of practice.

We realize that requiring EHRs to be certified to more than the minimum number of CQMs required by the Medicare and Medicaid EHR Incentive Programs may increase the burden on EHR vendors. However, in the interest of EPs, eligible hospitals, and CAHs being able to choose to report eCQMs that represent their patient populations, we would like to see EP vendors certify to all eCQMs that are in the EP selection list, or eligible hospital/CAH vendors certify to all eCQMs in the selection list for those stakeholders.

We are also considering a phased approach such that the number of CQMs required for the vendors to have

certified would increase each year until EHR products are required to certify all CQMs required for reporting by EPs, eligible hospitals, and CAHs. For example, in year one of this phased plan, we might require that EHRs be certified to at least 18 of 64 available CQMs for EPs and 22 of 29 available CQMs for eligible hospitals and CAHs; in year two, we might require at least 36 CQMs for EPs and all 29 CQMs for eligible hospitals and CAHs; in subsequent years of the plan, we would increase the number of required CQMs for EPs until the EHR is certified to all applicable CQMs for EPs, eligible hospitals, and CAHs.

We have also considered alternate plans that would require EHRs to be certified to more than the minimum number of CQMs required for reporting, but would not require the EHR to be certified to all available CQMs. For example, we might require that EHRs be certified to a certain core set of CQMs plus an additional 9 CQMs for EPs, and a certain core set of CQMs plus an additional 16 CQMs for eligible hospitals and CAHs, which the EHR vendor could choose from the list of available CQMs.

We note that the specifics of this plan would be outlined in separate notice-and-comment rulemaking such as the PFS or IPPS rules. We specifically seek comment on this issue of a plan to increase the number of CQMs to which an EHR is certified.

6. Electronic Reporting of CQMs

As previously stated in the Medicare and Medicaid EHR Incentive Programs Stage 2 final rule (77 FR 54051 through 54053), CQM data submitted by EPs, eligible hospitals, and CAHs are required to be captured, calculated and reported using certified EHR technology. We received numerous questions from stakeholders expressing confusion over what it means to capture data in certified EHR technology. Specifically, stakeholders question whether they may manually abstract data into the EHR from a patient's chart. We do not consider the manual abstraction of data from the EHR to be capturing the data using certified EHR technology. We believe that electronic information interfaced or electronically transmitted from non-certified EHR technology, such as lab information systems, automated blood pressure cuffs, and electronic scales, into the certified EHR, would satisfy the ''capture'' requirement, as long as that data is visible to providers in the EHR.

C. Demonstration of Meaningful Use and Other Issues

1. Demonstration of Meaningful Use

a. Common Methods of Demonstration in Medicare and Medicaid

We are proposing to continue our common method for demonstrating meaningful use in both the Medicare and Medicaid EHR Incentive Programs. The demonstration methods we adopt for Medicare would automatically be available to the States for use in their Medicaid programs.

b. Methods for Demonstration of the Stage 3 Criteria of Meaningful Use for 2017 and Subsequent Years

We are proposing to continue the use of attestation as the method for demonstrating that an EP, eligible hospital, or CAH has met the Stage 3 objectives and measures of meaningful use. We are proposing to continue the existing optional batch file process for attestation in lieu of individual Medicare EP attestation through our registration and attestion system. This batch reporting process ensures that meaningful use of certified EHR technology continues to be measured at the individual level, while promoting efficiencies for group practices that must submit attestations on large groups of individuals (77 FR 54089).

We would continue to leave open the possibility for CMS and the states to test options for demonstrating meaningful use that utilize existing and emerging HIT products and infrastructure capabilities. These options could involve the use of registries or the direct electronic reporting of measures associated with the objectives of meaningful use. We would not require any EP, eligible hospital, or CAH to participate in this testing in order to receive an incentive payment or avoid the payment adjustment.

For 2017 only, we are proposing changes to the attestation process for the meaningful use objectives and measures, which would allow flexibility for providers during this transitional year. These proposals are supported by a similar flexibility proposed in the requirements for the Edition of CEHRT a provider may use in 2017 as further discussed in section II.A.I.C.(1).(b).(3). of this proposed rule. In addition, we discuss the attestation changes proposed for CQM reporting in detail under section II.B.2.a. of this proposed rule.

(1) Meaningful Use Objective and Measures in 2017

In order to allow all providers to successfully transition to Stage 3 of meaningful use for a full year-long EHR reporting period in 2018, we are proposing to allow flexibility for the EHR Incentive Programs in 2017. This transition period would allow providers to establish and test their processes and workflows for Stage 3 of meaningful use prior to 2018. Specifically, for 2017, we are proposing that providers may either repeat a year at their current stage or move up stage levels. However, for 2017, a provider may not move backward in their progression. Under this proposal, providers who participated in Stage 1 in 2016 may choose to attest to the Stage 1 objective and measures, or they may move on to Stage 2 or Stage 3 objectives and measures for an EHR reporting period in 2017. Providers who participated in Stage 2 in 2016 may choose to attest to the Stage 2 objectives and measures or move on to Stage 3 objectives and measures for an EHR reporting period in 2017. However, under no circumstances, may providers return to Stage 1. In 2018, all providers, regardless of their prior participation or the stage level chosen in 2017, would be required to attest to Stage 3 objectives and measures for an EHR reporting period in 2018.

(2) CEHRT and Stage Flexibility in 2017

Based on the delays providers experienced with fully implementing the EHR technology certified to the 2014 Edition (as further described in the 2014 CEHRT Flexibility final rule (79 FR 52910 through 52933) we believe it is necessary to preemptively prepare for the upgrade to EHR technology certified to the 2015 Edition and the transition to Stage 3. Preparation for the upgrade would ensure that providers and developers have adequate time to certify, install, fully implement the software, and establish the processes and workflows for the objectives and measures for providers moving to the next stage of the EHR Incentive Programs. Accordingly, we propose allowing providers flexible CEHRT options for 2017. These options may impact the selection of objectives and measures to which a provider can attest. Specifically, under the CEHRT options for 2017, we propose that providers would have the option to continue to use EHR technology certified to the 2014 Edition, in whole or in part, for an EHR reporting period in 2017. We note that providers who use only the EHR technology certified to the 2014 Edition for an EHR reporting period in 2017 may not choose to attest to the Stage 3 objectives and measures as those objectives and measures require the support of EHR technology certified to the 2015 Edition.

Providers using only EHR technology certified in whole or in relevant part to the 2014 Edition certification criteria may attest to the objectives and measures of meaningful use in the following manner:

- If a provider first demonstrated meaningful use in 2015 or 2016, they may attest to Stage 1 objectives and measures or Stage 2 objectives and measures.
- If a provider first demonstrated meaningful use in any year prior to 2015, they may attest to the Stage 2 objectives and measures.

Providers using EHR technology certified in whole or in relevant part to the 2015 Edition certification criteria may elect to attest to the objectives and measures of meaningful use in the following manner:

- If a provider first demonstrated meaningful use in 2015 or 2016, they may attest to Stage 1 objectives and measures, Stage 2 objectives and measures, or Stage 3 objectives and measures if they have all the 2015 Edition functionality required to meet all Stage 3 objectives.
- If a provider first demonstrated meaningful use in any year prior to 2015, they may attest to Stage 2 objectives and measures, or Stage 3 objectives and measures if they have all the 2015 Edition functionality required to meet all Stage 3 objectives.

We note that all providers would be required to fully upgrade to EHR technology certified to the 2015 Edition for the EHR reporting period in 2018. We also reiterate that providers may elect to attest to Stage 3 of the program using EHR technology certified to the 2015 Edition beginning in 2017. We further stress that the use of 2011 CEHRT, although an option under the 2014 CEHRT Flexibility final rule (79 FR 52913 through 52914), is not an option under this proposal. However, as part of this proposal, we would like to seek comment on alternate flexibility options. Specifically, we are seeking comment on whether the flexible option to attest to Stages 1 or 2 should be limited to only those providers who could not fully implement EHR technology certified to the 2015 Edition in 2017. We are also seeking comment on whether those providers with fully implemented EHR technology certified to the 2015 Edition in 2017 should be required to attest to Stage 3 only in 2017. Finally, we seek comment on whether providers should not have the option to attest to Stage 3 in 2017 regardless of an upgrade to EHR technology certified to the 2015 Edition in 2017, and should instead be required to wait to demonstrate Stage 3 until 2018 using EHR technology certified to the 2015 Edition.

We welcome comments on these proposals.

(3) CQM Flexibility in 2017

In the 2014 CEHRT Flexibility final rule, we did not allow providers to separate their CQM reporting selection from the year of meaningful use objectives they reported on. We did not allow this reporting for a number of reasons including how we defined CQMs, as well as the number of CQMs reporting changes occurring between Stage 1 in 2011 through 2013, and Stage 1 and 2 in 2014. For further discussion, we direct readers to 79 FR 52927 through 52930.

To report CQMs for 2017, we propose to allow greater flexibility by proposing to split the use of CEHRT for CQM reporting from the use of CEHRT for the objectives and measures. This means that providers would be able to separately report CQMs using EHR technology certified to the 2015 Edition even if they use EHR technology certified to the 2014 Edition for the meaningful use objectives and measures for an EHR reporting period in 2017. Providers may also use EHR technology certified to the 2015 Edition for their meaningful use objectives and measures in 2017 and use EHR technology certified to the 2014 Edition for their CQM reporting for an EHR reporting period in 2017.

For an EHR reporting period in 2017, EPs, eligible hospitals, and CAHs may choose to report eCQMs electronically using the CQMs finalized for use in 2017 using the most recent version of the eCQMs (electronic specifications), which would be the electronic specifications of the CQMs published by CMS in 2016. Alternately, a provider may choose to continue to attest to the CQMs established for use in 2017 also using the most recent (2016 version) eCQM electronic specifications. These options are available for provider using either EHR technology certified to the 2014 Edition or EHR technology certified to the 2015 Edition. These flexible options for an EHR reporting period in 2017 are further discussed in sections II.B.2.a. of this proposed rule. An EP, eligible hospital, or CAH must use certified EHR technology, successfully attest to the meaningful use objectives and measures, and successfully submit CQMs to be a meaningful EHR user. We note that states may determine the form and method of CQM submission for participants in the Medicaid program subject to our approval as outline in sections II.B.3 and II.F.3. of this proposed rule. However, the selection of CQMs and the minimum reporting period are the same for providers in both Medicare and Medicaid as outlined in section II.B.3. of this proposed rule.

Similar to our rationale under the 2014 CEHRT Flexibility final rule (79 FR 52910 through 52933), we believe the proposals outlined for attestation in 2017 would allow providers the flexibility to choose the option which applies to their particular circumstances and use of CEHRT. Upon attestation, providers may select one of the proposed options available for their participation year and EHR Edition. The EHR Incentive Program Registration and Attestation System would then prompt the provider to attest to meeting the objectives, measures, and CQMs applicable under that option. We further propose that auditors would be provided guidance related to reviewing attestations associated with the options for using CEHRT in 2017, as was done for 2014.

We welcome comment on this proposal.

c. EHR Reporting Period in 2017 and Subsequent Years

We are proposing, with limited exceptions outlined in section II.F.1. of this proposed rule, that the EHR reporting period in 2017 would be a full calendar year for all providers. We encourage providers to begin Stage 3 in 2017. However, under the current timeline shown in Table 3, we recognize that providers first demonstrating meaningful use under Stage 1 in 2016 or 2017 or under Stage 2 in 2016 or 2017 must begin Stage 3 in 2018. We further recognize providers scheduled to begin Stage 3 in 2017 that instead choose to meet the Stage 2 criteria in 2017 must begin Stage 3 in 2018. However, in 2018, all providers, except as outlined in section II.F.1. of this proposed rule, must report based on a full calendar year EHR reporting period for the Stage 3 objectives and measures. In addition, in 2018, all providers must use EHR technology certified to the 2015 Edition for the full EHR reporting period in order to successfully demonstrate meaningful use.

For CQM reporting in 2018 and subsequent years, as outlined in section II.B.3 of this proposed rule, we are proposing that providers participating in the Medicare program must electronically report, where feasible, and that attestation to CQMs would no longer be an option except in circumstances where electronic reporting is not feasible. This would include providers facing circumstances which render them unable to

electronically report (such as a data submission system failure, natural disaster, or certification issue outside the control of the provider) who may attest to CQMs if they also attest that electronically reporting was not feasible for their demonstration of meaningful use for a given year.

We welcome public comment on this proposal.

2. Data Collection for Online Posting, Program Coordination, and Accurate Payments

We propose to continue posting Stage 1 and Stage 2 aggregate and individual performance and participation data resulting from the EHR Incentive programs online regularly for public use. We further note our intent to potentially publish the performance and participation data on Stage 3 objectives and measures of meaningful use in alignment with quality programs which utilize publicly available performance data such as physician compare.

In addition to the data already being collected under our regulations, as outlined in section III. of this proposed rule, we propose to collect the following information from providers to ensure providers keep their information up-to-date through the system of record for their National Provider Identifier (NPI) in the National Plan & Provider Enumeration System:

- Primary Practice Address (address, city, state zip, country code, etc.).
- Primary Business/Billing Address (address, city, state, zip, country code, etc.).
- Primary License information (for example, provide medical license in at least one state (or territory)).
- Contact Information (phone number, fax number, and contact email address).
- Health Information Exchange Information:

++ Such as DIRECT address required (if available).

++ If DIRECT address is not available, Electronic Service Information is required.

++ If DIRECT address is available, Electronic Service Information is optional in addition to DIRECT address.

We do not propose any changes to the registration for the Medicare and Medicaid EHR Incentive Programs.

3. Interaction With Other Programs

There are no proposed changes to the ability of providers to participate in the Medicare and Medicaid EHR Incentive Programs and other CMS programs. We continue to work on aligning the data collection and reporting of the various CMS programs, especially in the area of clinical quality measurement. See sections II.B.1. through II.B.6. of this proposed rule for the proposed alignment initiatives for CQMs.

D. Payment Adjustments and Hardship Exceptions

Sections 4101(b) and 4102(b) of the HITECH Act, amending sections 1848, 1853, and 1886 of the Act, require reductions in payments to EPs, eligible hospitals, and CAHs that are not meaningful users of certified EHR technology, beginning in CY 2015 for EPs, FY 2015 for eligible hospitals, and in cost reporting periods beginning in FY 2015 for CAHs.

1. Statutory Basis for Payment Adjustment and Hardship Exceptions for EPs

Section 1848(a)(7) of the Act provides for payment adjustments, effective for CY 2015 and subsequent years, for EPs as defined in 42 CFR 495.100, who are not meaningful EHR users during the relevant EHR reporting period for the year. Section 1848(a)(7) provides that in general, beginning in 2015, if an EP is not a meaningful EHR user for the EHR reporting period for the year, then the Medicare physician fee schedule (PFS) amount for covered professional services furnished by the EP during the year (including the fee schedule amount for purposes of determining a payment based on the fee schedule amount) is adjusted to equal the ''applicable percent'' of the fee schedule amount that would otherwise apply. The term ''applicable percent'' is defined in section 1848(a)(7)(A)(ii) of the Act as: (I) for 2015, 99 percent (or, in the case of an EP who was subject to the application of the payment adjustment [if the EP was not a successful electronic prescriber] under section 1848(a)(5) of the Act for 2014, 98 percent); (II) for 2016, 98 percent; and (III) for 2017 and each subsequent year, 97 percent.

In addition, section 1848(a)(7)(A)(iii) of the Act provides that if, for CY 2018 and subsequent years, the Secretary finds the proportion of EPs who are meaningful EHR users is less than 75 percent, the applicable percent shall be decreased by 1 percentage point for EPs who are not meaningful EHR users from the applicable percent in the preceding year, but that in no case shall the applicable percent be less than 95 percent.

Section 1848(a)(7)(B) of the Act provides that the Secretary may, on a case-by-case basis, exempt an EP who is not a meaningful EHR user for the reporting period for the year from the application of the payment adjustment if the Secretary determines that compliance with the requirements for being a meaningful EHR user would result in a significant hardship, such as in the case of an EP who practices in a rural area without sufficient internet access. The exception is subject to annual renewal, but in no case may an EP be granted an exception for more than 5 years.

We established regulations implementing these statutory provisions under 42 CFR 495.102. We refer readers to the final rules for Stages 1 and 2 (75 FR 44442 through 44448 and 77 FR 54093 through 54102) for more information.

2. EHR Reporting Period for Determining Whether an EP Is Subject to the Payment Adjustment for CY 2018 and Subsequent Calendar Years

Section 1848(a)(7)(E)(ii) of the Act provides the Secretary with broad authority to choose the EHR reporting period that will apply for purposes of determining the payment adjustments for CY 2015 and subsequent years. In the Stage 2 final rule (77 FR 54095 through 54097), we adopted a policy that the EHR reporting periods for the payment adjustments will begin and end prior to the year of the payment adjustment. We stated that this is based on our desire to avoid creating a situation in which it might be necessary either to recoup overpayments or make additional payments after a determination is made about whether the payment adjustment should apply, and the resulting implications for beneficiary coinsurance.

Specifically, we finalized under § 495.4 of the regulations that for EPs, the EHR reporting period for a payment adjustment year is the full calendar year that is 2 years before the payment adjustment year. For example, the full calendar year of 2015 would be the EHR reporting period for the CY 2017 payment adjustment year. We also finalized an exception to this rule for EPs who have never successfully attested to meaningful use. Stated generally, under this exception, for an EP who is demonstrating meaningful use for the first time, the EHR reporting period for a payment adjustment year is any continuous 90-day period. For a full description of this exception, including limitations on when the continuous 90-day period must occur in relation to the payment adjustment year and the deadlines for registration and attestation, we refer readers to the definition of ''EHR reporting period for a payment adjustment year'' under § 495.4 of the regulations and the discussion in the Stage 2 final rule (77 FR 54095 through 54096). We

established that these policies apply for the CY 2015 payment adjustment year and subsequent payment adjustment years.

However, in this Stage 3 proposed rule, we propose to eliminate the exception discussed previously for a 90-day EHR reporting period for new meaningful EHR users beginning with the EHR reporting period in 2017, with a limited exception for Medicaid EPs demonstrating meaningful use for the first time. We propose that for EPs who have successfully demonstrated meaningful use in a prior year as well as those who have not, the EHR reporting period for a payment adjustment year would be the full calendar year that is 2 years before the payment adjustment year. For example, for all EPs demonstrating meaningful use, the full CY 2017 would be the EHR reporting period for the CY 2019 payment adjustment year. To avoid a payment adjustment in CY 2019, EPs must demonstrate meaningful use of certified EHR technology for an EHR reporting period of the entire CY 2017. This policy would continue to apply in subsequent years.

As discussed in sections II.A.1.a. and II.F.1. of this proposed rule, we are proposing to maintain a 90-day EHR reporting period for the first payment year based on meaningful use for Medicaid EPs demonstrating meaningful use for the first time. We recognize that these EPs may be subject to payment adjustments under Medicare if they fail to demonstrate meaningful use, and thus we propose that the same 90-day EHR reporting period used for the Medicaid incentive payment would also apply for purposes of the Medicare payment adjustment for the payment adjustment year two years after the calendar year in which the provider demonstrates meaningful use. We note under our current policy, if an EP has never successfully demonstrated meaningful use, the EHR reporting period for a payment adjustment year is any continuous 90-day period that both begins in the calendar year 1 year before the payment adjustment year and ends at least 3 months before the end of such prior year. We do not propose to maintain this policy, and thus for Medicaid EPs who are new meaningful EHR users, the 90-day EHR reporting period for a payment adjustment year must occur within the calendar year that is 2 years before the payment adjustment year. These proposals for Medicaid EPs would apply beginning with the EHR reporting period in CY 2017.

We provide the following example:

Example A: If an EP has never successfully demonstrated meaningful use prior to CY 2017 and demonstrates under the Medicaid EHR Incentive Program that he or she is a meaningful EHR user for the first time in CY 2017, the EHR reporting period for the Medicaid incentive payment would be any continuous 90-day period within CY 2017. The same 90-day period would also serve as the EHR reporting period for the CY 2019 payment adjustment year under Medicare. This 90-day period would not serve as the EHR reporting period for the CY 2018 payment adjustment year under Medicare even if the EP registers for and attests to meaningful use by October 1, 2017. The EP would have to demonstrate meaningful use for an EHR reporting period of the full CY 2018 to earn an incentive payment under Medicaid for the CY 2018 payment year and avoid the payment adjustment under Medicare for the CY 2020 payment adjustment year.

We propose these changes to further our goal to align reporting requirements under the EHR Incentive Program and the reporting requirements for various CMS quality reporting programs, to respond to stakeholders who cited difficulty with following varying reporting requirements, and to simplify HHS system requirements for data capture. We further note that newly practicing EPs have the ability to apply for a hardship exception from the Secretary under § 495.102(d)(4)(ii), which provides for an exception from the payment adjustments for the 2 years after they begin practicing. We propose amendments to the definition of ''EHR reporting period for a payment adjustment year'' under § 495.4 to reflect these proposals. We welcome public comments on this proposal.

3. Exception to the Application of the Payment Adjustment to EPs in CY 2017 and Subsequent Years

As previously discussed, sections 1848(a)(7)(B) of the Act provides that the Secretary may, on a case-by-case basis, exempt an EP from the application of the payment adjustment in CY 2015 and subsequent calendar years if the Secretary determines that compliance with the requirements for being a meaningful EHR user will result in a significant hardship, such as an EP who practices in a rural area without sufficient internet access. As provided by the statute, the exception is subject to annual renewal, but in no case may an EP be granted an exception for more than 5 years. The statute does not require the Secretary to grant exceptions. However, as we stated in the Stage 2 final rule at 77 FR 54097, we believe that certain circumstances evidence the existence of a hardship, thereby justifying the need for an exception by the Secretary. Therefore, in the Stage 2 final rule, we finalized various types of hardship exceptions that EPs could apply for, which included insufficient internet access, newly practicing EPs, extreme circumstances outside of an EP's control, lack of control over the availability of CEHRT for EPs practicing in multiple locations, lack of face-to-face patient interactions and lack of need for follow-up care, and certain primary specialties. For further discussion of the hardship exceptions, we refer readers to the Stage 2 final rule at 77 FR 54097 through 54101 and 42 CFR 495.102(d)(4).

In this Stage 3 proposed rule, we propose no changes to the types of exceptions previously finalized for EPs, nor do we propose any new types of exceptions for 2017 and subsequent years. Accordingly, we propose that the exceptions continue as previously finalized.

4. Statutory Basis for Payment Adjustments and Hardship Exceptions for Eligible Hospitals

Section 1886(b)(3)(B)(ix)(I) of the Act, as amended by section 4102(b)(1) of the HITECH Act, provides for an adjustment to the applicable percentage increase to the IPPS payment rate for those eligible hospitals that are not meaningful EHR users for the associated EHR reporting period for a payment adjustment year, beginning in FY 2015. Specifically, section 1886(b)(3)(B)(ix)(I) of the Act provides that, for FY 2015 and each subsequent fiscal year, an eligible hospital that is not ''a meaningful EHR user . . . for an EHR reporting period'' will receive a reduced update to the IPPS standardized amount. This reduction applies to ''three-quarters of the percentage increase otherwise applicable'' prior to the application of statutory adjustments under sections 1886(b)(3)(B)(viii), 1886(b)(3)(B)(xi), and 1886(b)(3)(B)(xii) of the Act, or three-quarters of the applicable market basket update. The reduction to three-quarters of the applicable update for an eligible hospital that is not a meaningful EHR user will be ''33⅓ percent for FY 2015, 66⅔ percent for FY 2016, and 100 percent for FY 2017 and each subsequent FY.'' In other words, for eligible hospitals that are not meaningful EHR users, the Secretary must reduce the applicable percentage increase (prior to the application of other statutory adjustments) by 25 percent (33⅓ of 75 percent) in FY 2015,

50 percent (66⅔ percent of 75 percent) in FY 2016, and 75 percent (100 percent of 75 percent) in FY 2017 and subsequent years. Section 4102(b)(1)(B) of the HITECH Act also provides that the reduction shall apply only with respect to the fiscal year involved and the Secretary shall not take into account such reduction in computing the applicable percentage increase for a subsequent fiscal year.

Section 1886(b)(3)(B)(ix)(II) of the Act, as amended by Section 4102(b)(1) of the HITECH Act, provides that the Secretary may, on a case-by-case basis, exempt a hospital from the application of the applicable percentage increase adjustment for a fiscal year if the Secretary determines that requiring such hospital to be a meaningful EHR user will result in a significant hardship, such as in the case of a hospital in a rural area without sufficient internet access. This section also provides that such determinations are subject to annual renewal, and that in no case may a hospital be granted an exception for more than 5 years.

5. Applicable Market Basket Update Adjustment for Eligible Hospitals That Are Not Meaningful EHR Users for FY 2019 and Subsequent Fiscal Years

Section 412.64(d) of the regulations sets forth the adjustment to the percentage increase in the market basket index for those eligible hospitals that are not meaningful EHR users for the EHR reporting period for a payment year, beginning in FY 2015.

6. EHR Reporting Period for Determining Whether a Hospital Is Subject to the Market Basket Update Adjustment for FY 2018 and Subsequent Fiscal Years

Section 1886(b)(3)(B)(ix)(IV) of the Act makes clear that the Secretary has discretion to specify as the EHR reporting period ''any period (or periods)'' that will apply ''with respect to a fiscal year.'' In the Stage 2 final rule at 77 FR 54104 through 54105, we finalized the applicable EHR reporting period for purposes of determining whether an eligible hospital is subject to the payment adjustment.

As with EPs, we finalized that the EHR reporting period for the payment adjustment year for eligible hospitals will begin and end prior to the year of the payment adjustment. We finalized under § 495.4 of the regulations that for eligible hospitals, the EHR reporting period for a payment adjustment year is the full federal fiscal year that is 2 years before the payment adjustment year. We established this policy beginning with the FY 2015 payment adjustment year and continuing in subsequent years. For example, the full federal fiscal year of 2015 would be the EHR reporting period for the FY 2017 payment adjustment year. However, in this Stage 3 proposed rule, beginning in 2017, we propose to change the EHR reporting period for a payment adjustment year for eligible hospitals from a fiscal year basis to a calendar year basis. Specifically, we propose to revise the definition of ''EHR reporting period for a payment adjustment year'' under § 495.4 such that the EHR reporting period for a payment adjustment year for an eligible hospital would be the full calendar year that is 2 years before the payment adjustment year. For example, the entire CY 2017 would be the EHR reporting period used to determine whether the payment adjustment would apply for an eligible hospital for FY 2019. This change would apply beginning with the CY 2017 EHR reporting period for purposes of the FY 2019 payment adjustment year, and continue to apply in subsequent years. We note that eligible hospitals would have ample time to adjust to the new calendar year reporting timeframe given that under our current policy, the EHR reporting period occurs prior to the payment adjustment year. We further believe that aligning all providers, including eligible hospitals, to a calendar year EHR reporting timeframe for purposes of the payment adjustment, would simplify reporting for all providers, especially for larger providers with diverse systems and groups. In addition, placing all providers, including eligible hospitals, onto a calendar year timeframe would further simplify HHS system requirements for data capture and would move the EHR Incentive Program another step closer to alignment with various CMS quality reporting programs. We welcome comments on this proposal.

Further, in the Stage 2 final rule, we finalized an exception to the general rule of a full federal fiscal year EHR reporting period for eligible hospitals that have never successfully attested to meaningful use. Stated generally, under this exception, for an eligible hospital that is demonstrating meaningful use for the first time, the EHR reporting period for a payment adjustment year is any continuous 90-day period. For a full description of this exception, including limitations on when the continuous 90-day period must occur in relation to the payment adjustment year and the deadlines for registration and attestation, we refer readers to the definition of ''EHR reporting period for a payment adjustment year'' under § 495.4 of the regulations and the discussion in the Stage 2 final rule (77 FR 54104 and 54105).

However, in this Stage 3 proposed rule, we propose to eliminate this exception for eligible hospitals that are new meaningful EHR users beginning with the EHR reporting period in 2017, with a limited exception for Medicaid eligible hospitals demonstrating meaningful use for the first time. As explained previously, we propose that for eligible hospitals that have successfully demonstrated meaningful use in a prior year as well as those that have not, the EHR reporting period for a payment adjustment year would be the full calendar year that is 2 years before the payment adjustment year. For example, for all eligible hospitals, the full CY 2017 would be the EHR reporting period for the FY 2019 payment adjustment year. This policy would continue to apply in subsequent years.

Though, as discussed in sections II.A.1.a. and II.F.1. of this proposed rule, for Medicaid eligible hospitals demonstrating meaningful use for the first time, we are proposing to maintain a 90-day EHR reporting period for the first payment year based on meaningful use. We recognize that these eligible hospitals may be subject to payment adjustments under Medicare if they fail to demonstrate meaningful use, and thus we propose that the same 90-day EHR reporting period used for the Medicaid incentive payment would also apply for purposes of the Medicare payment adjustment for the payment adjustment year 2 years after the calendar year in which the provider demonstrates meaningful use. We note under our current policy, if an eligible hospital has never successfully demonstrated meaningful use, the EHR reporting period for a payment adjustment year is any continuous 90-day period that both begins in the federal fiscal year 1 year before the payment adjustment year and ends at least 3 months before the end of such prior year. We do not propose to maintain this policy, and thus for Medicaid eligible hospitals that are new meaningful EHR users, the 90-day EHR reporting period for a payment adjustment year must occur within the calendar year that is 2 years before the payment adjustment year. These proposals for Medicaid eligible hospitals would apply beginning with the EHR reporting period in CY 2017.

We provide the following example:

Example A: If an eligible hospital has never successfully demonstrated meaningful use prior to CY 2017 and demonstrates under the Medicaid EHR

Incentive Program that it is a meaningful EHR user for the first time in CY 2017, the EHR reporting period for the Medicaid incentive payment would be any continuous 90-day period within CY 2017. The same 90-day period would also serve as the EHR reporting period for the FY 2019 payment adjustment year under Medicare. This 90-day period would not serve as the EHR reporting period for the FY 2018 payment adjustment year under Medicare even if the eligible hospital registers for and attests to meaningful use by July 1, 2017. The eligible hospital would have to demonstrate meaningful use for an EHR reporting period of the full CY 2018 to earn an incentive payment under Medicaid for the 2018 payment year and avoid the payment adjustment under Medicare for the FY 2020 payment adjustment year.

Like our proposal to move eligible hospitals to a calendar year timeframe, we believe that removing the continuous 90-day EHR reporting period for most eligible hospitals would simplify reporting for providers, especially those hospitals with diverse groups and systems. In addition, eliminating the 90-day EHR reporting period would move the EHR Incentive Program one step closer to alignment within the program and with CMS quality reporting programs and would simplify HHS system requirements for data capture. Therefore, moving eligible hospitals to a calendar year EHR reporting period for the payment adjustment years, as well as requiring all providers (EPs and hospitals) to report based on the same full year calendar timeframe would accomplish these goals and be responsive to prior public comments asking us to simplify the EHR Incentive Program.

We propose amendments to the definition of ''EHR reporting period for a payment adjustment year'' under § 495.4 to reflect these proposals.

We note that hospitals that are eligible under both the Medicaid and Medicare incentive programs, and that are attesting for the Medicaid program, do not need to separately attest in the Medicare program in 2017 and subsequent years, because the statute does not allow for Medicare EHR incentive payments to eligible hospitals after FY 2016. If a hospital eligible under both programs is demonstrating meaningful use for the first time, and using a continuous 90-day EHR reporting period under the Medicaid program, it could attest for the Medicaid program only, and still avoid the Medicare payment adjustment that is 2 years after the calendar year in which the EHR reporting period occurs. However, if a hospital eligible under both programs chooses also to attest for the Medicare program, it would be required to complete an EHR reporting period of 1 full calendar year to avoid the Medicare payment adjustment that is 2 years after that calendar year.

We welcome public comments on these proposals.

7. Exception to the Application of the Market Basket Update Adjustment to Hospitals in FY 2019 and Subsequent Fiscal Years

As stated previously, section 1886(b)(3)(B)(ix)(II) of the Act, as amended by section 4102(b)(1) of the HITECH Act, provides that the Secretary, may, on a case-by-case basis, exempt a hospital from the application of the applicable percentage increase payment adjustment for a fiscal year if the Secretary determines that compliance with the requirements for being a meaningful EHR user will result in a significant hardship, such as an eligible hospital located in a rural area without sufficient internet access. Section 1886(b)(3)(B)(ix)(III) also provides that the exception is subject to annual renewal, but in no case may a hospital be granted an exception for more than 5 years. The Secretary's hardship exception authority is discretionary.

As we explained in the Stage 2 final rule at 77 FR 54105 through 54106, we believe that certain circumstances may constitute a hardship that would warrant the Secretary's use of the exception authority. Therefore, in the Stage 2 final rule, we finalized various types of hardship exceptions for which eligible hospitals may apply, which included lack of insufficient internet access, extreme circumstances outside of a hospital's control, and the establishment of new hospitals. For further discussion of the hardship exceptions, we refer readers to the Stage 2 final rule at 77 FR 54105 through 54108 as well as 42 CFR 412.64(d)(4).

In this Stage 3 proposed rule, we propose no changes to the types of exceptions previously finalized for eligible hospitals, nor do we propose any new exceptions for eligible hospitals. Accordingly, for Stage 3, we propose to continue the hardship exceptions for 2017 and subsequent years as previously finalized.

8. Statutory Basis for Payment Adjustments to CAHs

Section 4102(b)(2) of the HITECH Act amended section 1814(l) of the Act to include an adjustment to a CAH's Medicare reimbursement for inpatient services if the CAH is not a meaningful EHR user for an EHR reporting period. The adjustment will be made for cost reporting periods that begin in FY 2015, FY 2016, FY 2017, and each subsequent FY thereafter. Specifically, sections 1814(l)(4)(A) and (B) of the Act provide that, if a CAH does not demonstrate meaningful use of CEHRT for an applicable EHR reporting period, then for a cost reporting period beginning in FY 2015, the CAH's reimbursement shall be reduced from 101 percent of its reasonable costs to 100.66 percent of reasonable costs. For a cost reporting period beginning in FY 2016, its reimbursement would be reduced to 100.33 percent of its reasonable costs. For a cost reporting period beginning in FY 2017 and each subsequent fiscal year, its reimbursement would be reduced to 100 percent of reasonable costs.

However, as provided for eligible hospitals, a CAH, may, on a case-by-case basis, be granted an exception from this adjustment if CMS or its Medicare contractor determines, on an annual basis, that a significant hardship exists, such as in the case of a CAH in a rural area without sufficient internet access. However, in no case may a CAH be granted this exception for more than 5 years.

9. Reduction of Reasonable Cost Reimbursement in FY 2015 and Subsequent Years for CAHs That Are Not Meaningful EHR Users

a. Applicable Reduction of Reasonable Cost Payment Reduction in FY 2015 and Subsequent Years for CAHs That Are Not Meaningful EHR Users

In the Stage 1 final rule (75 FR 44564), we finalized the regulations regarding the CAH adjustment at § 495.106(e) and § 413.70(a)(6).

b. EHR Reporting Period for Determining Whether a CAH Is Subject to the Applicable Reduction of Reasonable Cost Payment in FY 2015 and Subsequent Years

In Stage 2, we amended the definition of the EHR reporting period that would apply for purposes of the payment adjustment for CAHs under § 495.4 (77 FR 54109 and 54110). For CAHs, this is the full federal fiscal year that is the same as the payment adjustment year (unless a CAH is in its first year of demonstrating meaningful use, in which case a continuous 90-day EHR reporting period within the payment adjustment year would apply). The adjustment applies based upon the cost reporting period that begins in the payment adjustment year (that is, FY 2015 and

thereafter). Thus, if a CAH is not a meaningful EHR user for FY 2015, and thereafter, then the payment adjustment is applied to the CAH's reasonable costs incurred in a cost reporting period that begins in the affected fiscal year as described in § 413.70(a)(6)(i). We further finalized that CAHs submit their attestations on meaningful use by November 30 of the following fiscal year. For example, if a CAH is attesting that it was a meaningful EHR user for FY 2015, the attestation must be submitted no later than November 30, 2015. Such an attestation or lack thereof, will then affect interim payments to the CAH made after December 1 of the applicable fiscal year. If the cost reporting period ends prior to December 1 of the applicable fiscal year, then any applicable payment adjustment will be made through the cost report settlement process.

Under this Stage 3 proposed rule, we are proposing a change to the EHR reporting period that would apply for the payment adjustments for CAHs, beginning with the FY 2017 payment adjustment year. First, similar to what we proposed for eligible hospitals previously, we propose that the EHR reporting period for a payment adjustment year for CAHs would be a full calendar year, rather than a full federal fiscal year. We propose the EHR reporting period for a payment adjustment year would be the calendar year that overlaps the last 3 quarters of the federal fiscal year that is the payment adjustment year. For example, in order for a CAH to avoid application of the adjustment to its reasonable costs incurred in a cost reporting period that begins in FY 2017, the CAH must demonstrate it is a meaningful EHR user for an EHR reporting period of the full CY 2017. This proposed change would mean that the EHR reporting period would no longer precisely align with the payment adjustment year. We propose amendments to the definition of ''EHR reporting period for a payment adjustment year'' under § 495.4 to reflect these proposals.

In the Stage 2 final rule, we note the process for the implementation of a payment adjustment to CAH cost reports in relation to the EHR reporting period attestation deadline (77 FR 54109 and 54110). Under our Stage 3 proposal, we would need to move the CAH attestation deadline in order to accommodate the change to a calendar year-based EHR reporting period. Therefore, we propose to move the CAH attestation deadline to the last day in February following the end of the EHR reporting period as we currently allow for EPs. Any accounting shifts that occur as a result from the change to a calendar year-based EHR reporting period can be accommodated through the cost reporting and settlement process. The CAH must attest no later than 2 months (February 28 or February 29 if applicable) following the close of the EHR reporting period at the end of each calendar year to avoid the payment adjustment. Such an attestation or lack thereof, will then affect interim payments to the CAH made after March 1 of the applicable federal fiscal year. If the cost reporting period ends prior to March 1 of the applicable fiscal year, then any applicable payment adjustment will be made through the cost report settlement process.

We are proposing this change to the EHR reporting period for the payment adjustment year to further align most providers to a calendar year-based EHR reporting period. We believe that the change to calendar year reporting for CAHs is feasible given that the cost reporting and cost settlement processes is unique to CAHs under the Medicare EHR Incentive Program. Unlike eligible hospitals or EPs, who use a claims processing system to determine the payment adjustment under the Medicare EHR Program, CAHs are required to file an annual Medicare cost report that is typically for a consecutive 12-month period. The cost report reflects the inpatient statistical and financial data that forms the basis of the CAH's Medicare reimbursement. Interim Medicare payment may be made to the CAH during the cost reporting period based on the previous year's data. Cost reports are filed with the CAH's Medicare contractor after the close of the cost reporting period, and the data on the cost report are subject to the reconciliation and settlement process prior to a final Medicare payment being made. The proposed change to a calendar year EHR reporting period for CAHs would not significantly impact the ability to implement the payment adjustments in the cost report reconciliation process for either CAHs or CMS. It would only shift the potential date where the reconciliation of any payment adjustment in the cost reporting process may occur. These payments would still be subject to the reconciliation and settlement process prior to a final Medicare payment being made.

For example, currently CAHs must file their attestations on meaningful use by November 30 of the federal fiscal year following the close of the federal fiscal year in which the EHR reporting period occurs. Under our current system, if a CAH is attesting that it was a meaningful EHR user for FY 2015, the attestation must be submitted not later than November 30, 2015. A payment adjustment applied if the CAH does not successfully attest would affect interim payment to the CAH made after December 1 of 2015. If the cost reporting period ends prior to December 1, 2015, then any applicable payment adjustment will be made under the cost reporting settlement process.

In an example of a similar scenario under the new proposal, a CAH that does not successfully demonstrate meaningful use based on a calendar year EHR reporting period in 2017 (January 1, 2017 through December 31, 2017) would be subject to a payment adjustment applied to its reasonable costs incurred in the cost reporting period beginning in FY 2017 (October 1, 2017 through September 30, 2018). To avoid the payment adjustment in this example, the CAH must attest no later than February 28, 2018 to demonstrate meaningful use for an EHR reporting period in 2017. If the CAH does not attest by February 28, 2018, a payment adjustment would then affect interim payments to the CAH made after March 1, 2018. If the cost reporting period ends prior to March 1, 2018, then any applicable payment adjustment would be made through the cost report settlement process. We note that this is reflective of a similar policy in the Stage 2 final rule addressing the process for CAH payment adjustments with an attestation deadline of November 30 in a given year and direct readers to 77 FR 54110 for further information on this policy.

Second, as noted previously, and outlined in the definition of ''EHR reporting period for a payment adjustment year'' under § 495.4, we established an exception for first-time CAH meaningful EHR users. Under our current policy, if a CAH is demonstrating it is a meaningful EHR user for the first time in the payment adjustment year, the applicable EHR reporting period is any continuous 90-day period within the federal fiscal year that is the payment adjustment year.

For this Stage 3 proposed rule, we propose to eliminate this exception for CAHs that are new meaningful EHR users beginning with the EHR reporting period in 2017, with a limited exception for CAHs demonstrating meaningful use for the first time under the Medicaid EHR Incentive Program. As discussed in II.A.1.a. and II.F.1. of this proposed rule, for CAHs that demonstrate meaningful use for the first time under Medicaid, we are proposing to maintain a 90-day EHR reporting period for the first payment year based on meaningful use. We recognize that these CAHs may be

subject to payment adjustments under Medicare if they fail to demonstrate meaningful use, and thus we propose that the same 90-day EHR reporting period used for the Medicaid incentive payment would also apply for purposes of the Medicare payment adjustment.

We propose amendments to the definition of ''EHR reporting period for a payment adjustment year'' under § 495.4 to reflect these proposals. Example A: If a CAH has never successfully demonstrated meaningful use prior to CY 2017 and demonstrates under the Medicaid EHR Incentive Program that it is a meaningful EHR user for the first time in CY 2017, the EHR reporting period for the Medicaid incentive payment would be any continuous 90-day period within CY 2017. The same 90-day period would also serve as the EHR reporting period for the FFY 2017 payment adjustment year under Medicare.

Like our proposal to move CAHs to a calendar year timeframe, we believe that removing the continuous 90-day EHR reporting period for most CAHs would simplify reporting for providers, especially those CAHs with diverse groups and systems. In addition, eliminating the 90-day EHR reporting period would move the EHR Incentive Program one step closer to alignment within the program and with CMS quality reporting programs, and would simplify HHS system requirements for data capture. Therefore, moving CAHs to a calendar year EHR reporting period for the payment adjustment year, as well as requiring most providers (EPs, CAHs, and eligible hospitals) to report based on the same full year calendar timeframe would accomplish these goals and be responsive to prior public comments asking us to simplify the EHR Incentive Program.

We welcome public comments on these proposals.

10. Administrative Review Process of Certain Electronic Health Record Incentive Program Determinations

In the Stage 2 final rule (77 FR 54112 through 54113), we discussed an administrative appeals process for both Stages 1 and 2 of meaningful use. We believe this appeals process is primarily procedural and does not need to be specified in regulation. We have developed guidance on the appeals process, which is available on our Web site at *www.cms.gov/EHRIncentivePrograms.* We propose no changes in this proposed rule and intend to continue to specify the appeals process in guidance available on our Web site.

E. Medicare Advantage Organization Incentive Payments

We are not proposing any changes to the existing policies and regulations for Medicare Advantage (MA) organizations. Our existing policies and regulations include provisions concerning the EHR incentive payments to qualifying MA organizations and the payment adjustments for 2015 and subsequent MA payment adjustment years. (For more information on MA organization incentive payments, we refer readers to the final rules for Stages 1 and 2 (75 FR 44468 through 44482 and 77 FR 54113 through 54119).)

F. The Medicaid EHR Incentive Program

The proposals discussed in sections II.F.1. through II.F.3. of this proposed rule would be applicable upon the effective date of the final rule, not when Stage 3 of meaningful use of certified EHR technology begins, unless otherwise indicated.

1. EHR Reporting Period for First Year of Meaningful Use

We are proposing amendments to the definitions of ''EHR reporting period'' and ''EHR reporting period for a payment adjustment year'' in § 495.4 to shift the EHR reporting periods for eligible hospitals and CAHs to periods that are based on the calendar year, not the federal fiscal year, and to establish a full calendar year as the EHR reporting period or EHR reporting period for a payment adjustment year for almost all providers beginning in 2017. However, we are also proposing a limited exception under which Medicaid EPs and eligible hospitals demonstrating meaningful use for the first time could use any continuous 90-day EHR reporting period within the calendar year. This EHR reporting period for Medicaid providers demonstrating meaningful use for the first time would apply both for purposes of receiving an incentive payment in the Medicaid program and for purposes of avoiding the payment adjustment under the Medicare program for the payment adjustment year that is two years after the calendar year in which the provider first demonstrates meaningful use for an EHR reporting period. Under this proposal, Medicaid EPs and eligible hospitals would have an EHR reporting period of any continuous 90-day period in the calendar year that is the payment year, for their first payment year based on meaningful use, beginning in 2017. We note that hospitals that are eligible under both the Medicaid and Medicare incentive programs, and that are attesting for the Medicaid program, do not need to separately attest in the Medicare program in 2017 and subsequent years, because the statute does not allow for Medicare EHR incentive payments to eligible hospitals after FY 2016. If a hospital eligible under both programs is demonstrating meaningful use for the first time, and using a continuous 90-day EHR reporting period under the Medicaid program, it could attest for the Medicaid program only, and still avoid the Medicare payment adjustment that is 2 years after the calendar year in which the EHR reporting period occurs. However, if a hospital eligible under both programs chooses also to attest for the Medicare program, it would be required to complete an EHR reporting period of 1 full calendar year to avoid the Medicare payment adjustment that is 2 years after that calendar year. We note that, consistent with the other proposed amendments to § 495.4 discussed previously, this proposal would change the EHR reporting period for eligible hospitals from one that is based on the federal fiscal year to one that is based on the calendar year, beginning in 2017. For further discussion of the relationship between the 90-day EHR reporting period under the Medicaid EHR Incentive Program and the payment adjustments under Medicare, we refer readers to section II.D. of this proposed rule.

This policy would allow Medicaid providers flexibility in their first year of demonstrating meaningful use. It also would reduce the burden on states to implement significant policy and system changes in preparation for Stage 3, as the 90-day period for the first year of meaningful use is consistent with our previous policies and meaningful use timelines.

2. Reporting Requirements

a. State Reporting on Program Activities

As discussed in section II.A.1.c.(1).(b).(iii). of this proposed rule, we are adding a new provision at § 495.316(d)(2)(iii) to provide states with flexibility regarding the Stage 3 public health and clinical data registry reporting objective.

We also propose to amend § 495.316(c), as well as add a new paragraph § 495.316(f), to formalize the process of how states report to us annually on the providers that have attested to adopt, implement, or upgrade (AIU), or that have attested to meaningful use. Under this proposal, states would follow a structured submission process, in the manner prescribed by CMS, which would include a new annual reporting

deadline. We propose to require states to submit annual reports to CMS within 45 days of the end of the second quarter of each federal fiscal year.

We propose to regularize the timing of the annual reporting process described in § 495.316 to ensure more timely annual reports and allow for clearer communication to states on when the reports should be submitted to CMS. In addition, CMS and states would be able to more effectively track the progress of states' incentive program implementation and oversight as well as provider progress in achieving meaningful use. Predictable deadlines for annual reporting would permit CMS and the states to more quickly compare and assess overall program impact each year.

We are also considering changes to the data that the annual reporting requirements outlined in § 495.316(d) require states to include in their annual reports. Specifically, we are considering whether to remove the requirement that states report information about practice location for providers that qualify for incentive payments on the basis of having adopted, implemented, or upgraded certified EHR technology or on the basis of demonstrating they are meaningful users of certified EHR technology. While we believe that this data is useful to both CMS and the states for program implementation purposes, we believe the benefits of including it in state reports might be outweighed by the burdens to states of reporting it. Therefore, we are seeking more information on state burdens and costs associated with complying with this requirement. We solicit comments both on the burdens associated with the requirement to report practice location information for providers that receive incentive payments through the Medicaid EHR Incentive Program, and on the benefits of including this information in state reports.

We propose to amend § 495.352 to formalize the process of how states submit quarterly progress reports on implementation and oversight activities and to specify the elements that should be included in the quarterly reports. Under this proposal, states would follow a structured submission process, in the manner prescribed by CMS. We propose that states would report on the following activities: State system implementation dates; provider outreach; auditing; state-specific SMHP tasks; state staffing levels and changes; the number and type of providers that qualified for an incentive payment on the basis of demonstrating that they are meaningful EHR users of certified EHR technology and the amounts of incentive payments; and the number and type of providers that qualified for an incentive payment on the basis of having adopted, implemented, or upgraded certified EHR technology and the amounts of incentive payments.

We propose these changes to the quarterly reporting process described in § 495.352 so that CMS and states can better track state implementation and oversight activity progress in a way that would permit CMS and the states to compare overall programmatic and provider progress. We also expect that streamlined and enhanced quarterly progress reporting would lead to an improvement in overall data quality that would help inform future meaningful use activity across states.

We would like to include a deadline for states' quarterly reporting under the proposed amendments to § 495.352, and are considering requiring states to submit quarterly progress reports to CMS within 30 days after the end of each federal fiscal year quarter. We believe that a set deadline would improve timeliness and communication, but we do not want to set a deadline that is overly burdensome for a report that must be submitted quarterly. We seek public comment on the deadline we are considering.

b. State Reporting on Meaningful EHR Users

Starting in FY 2015 for eligible hospitals and CY 2015 for EPs, providers that fail to demonstrate meaningful use for an applicable EHR reporting period will be subject to downward payment adjustments under Medicare. As discussed in the Stage 2 final rule (77 FR 54094), EPs who are meaningful EHR users under the Medicaid EHR Incentive Program for an applicable EHR reporting period will be considered meaningful EHR users for that period for purposes of avoiding the Medicare payment adjustments. Currently, hospitals eligible for both Medicaid and Medicare incentive payments attest in both the Medicare and Medicaid systems to earn an incentive payment in both programs. The statute does not authorize Medicare EHR incentive payments to eligible hospitals after FY 2016. To avoid duplicative reporting, hospitals eligible under both programs will not be required to attest in both programs beginning in 2017. Therefore, we must have accurate and timely data from states regarding both EPs and eligible hospitals that have successfully demonstrated meaningful use for each payment year to ensure that meaningful EHR users in the Medicaid EHR Incentive Program are appropriately exempted from the Medicare payment adjustment for the applicable payment adjustment year. This additional reporting is necessary because the electronic data currently contained in the National Level Repository are insufficient to determine which Medicaid providers should be exempted from the Medicare payment adjustments in an accurate and timely manner. Accordingly, we propose to add new paragraphs (g) and (h) to § 495.316 to require that states submit reports on a quarterly basis that identify certain providers that attested to meaningful use through the Medicaid EHR Incentive Program for each payment year. Under this proposal, states would submit quarterly reports for Medicaid EPs and eligible hospitals that successfully attest to meaningful use for each payment year.

We propose that states would report quarterly, in the manner prescribed by CMS, information on each provider that successfully attests to meaningful use, regardless of whether the provider has been paid yet. The report would be required to specify the Medicaid state and payment year. For each EP or eligible hospital listed in the report, the state would also specify the Payment Year Number, the NPI for EPs and the CCN for eligible hospitals, the Attestation Submission Date, the State Qualification (as either meaningful use or blank), and the State Qualification Date (the beginning date of the reporting period in which successful meaningful use attestation was achieved by the EP or eligible hospital). The EP or eligible hospital's ''payment year number'' refers to the number of years that the provider has been paid in the EHR Incentive Program; so, for example, this would be ''2'' for the 2014 payment year if the provider received payments for 2013 and 2014. States would have this data, even for providers that have previously received an incentive payment through the Medicare EHR Incentive Program. If the state is reporting a disqualification, then the state would leave the State Qualification field blank. If applicable, in the cases of EPs or eligible hospitals previously identified as meaningful EHR users, the state would be required to specify the State Disqualification and State Disqualification Date (that is, the beginning date of the EHR reporting period during which an EP or eligible hospital was found not to meet the definition of a meaningful EHR user).

Under this proposal, states would submit this information beginning with payment year 2013 data. The reports would cover back to the 2013 payment year because that would be the EHR

reporting period for the 2015 Medicare payment adjustment year under § 495.4. Providers that successfully attested to meaningful use for 2013 would be exempt from the Medicare payment adjustment in 2015.

Under this proposal, states would not be required to include information about certain providers in their reports. We recognize that several provider types that are eligible for the Medicaid EHR Incentive Program are not subject to the Medicare payment adjustments. Accordingly, states would not be required to report on those EPs who are eligible for the Medicaid EHR Incentive Program on the basis of being a nurse practitioner, certified nurse-midwife, or physician assistant.

3. Clinical Quality Measurement for the Medicaid Program

States are, and will continue in Stage 3 to be, responsible for determining whether and how electronic reporting of CQMs would occur, or whether they wish to allow reporting through attestation. This is consistent with our policy in the Stage 2 final rule (77 FR 54075). If a state does require electronic reporting, the state is responsible for sharing the details on the process with its provider community. We anticipate that whatever means states have deployed for capturing Stages 1 and 2 clinical quality measures electronically would be similar for reporting in 2017 and subsequent years. However, we note that subject to our prior approval, this is within the states' purview. States that wish to establish the method and requirements for electronically reporting would continue to be required to do so through the SMHP submission, subject to our prior approval.

To further our goals of alignment and avoiding duplicative reporting across quality reporting programs, we would recommend that states include a narrative in their SMHP for CY 2017 describing how their proposed meaningful use CQM data submission strategy aligns with their State Medicaid Quality Strategy and report which certified EHR technology requirements they mandate for eCQM reporting.

For more information on requirements around the State Medicaid Quality Strategy, see *http://medicaid.gov/Federal-Policy-Guidance/Downloads/SHO-13-007.pdf.*

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to evaluate fairly whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The following is a discussion of the requirements contained in this proposed regulation that we believe are subject to PRA and collection of information requirements (ICRs). The projected numbers of EPs, eligible hospitals, and CAHs, MA organizations, MA EPs and MA-affiliated hospitals are based on the numbers used in the impact analysis assumptions as well as estimated federal costs and savings in the section V.C. of this proposed rule. The actual burden would remain constant for all of Stage 3 as EPs, eligible hospitals, and CAHs would only need to attest that they have successfully demonstrated meaningful use in 2017 and annually thereafter. The only variable from year-to-year in Stage 3 would be the number of respondents, as noted in the impact analysis assumptions. For the purposes of this analysis, we are focusing only on 2017, the first year in which a provider may participate in Stage 3 of the Medicare EHR Incentive Program. We do not believe the burden for EPs, eligible hospitals, and CAHs participating in Stages 1 and 2 prior to 2017 would be different from the Agency Information Collection Activities (75 FR 65354) based on this proposed rule. Beginning in 2012, Medicare EPs, eligible hospitals, and CAHs have the option to electronically report their clinical quality measures through the respective electronic reporting pilots. For eligible hospitals and CAHs, the burden is discussed in the CY 2012 Hospital Outpatient Prospective Payment System final rule with comment period (76 FR 73450 through 73451).

As discussed in section I.A.1.a. of this proposed rule, Stage 3 is intended to build on Stages 1 and 2 with a focus on advanced use of certified EHR technology to promote improved patient outcomes while assuring that the framework is flexible and does not hinder innovation. In this proposed rule, the definition of meaningful use with associated reporting requirements would replace all prior definitions and requirements beginning in 2018. At that point, all eligible providers would be required to report only Stage 3 requirements on an annual basis. For 2017, providers may simply repeat their current status at Stage 1 or Stage 2, or move on to Stage 3. The same reporting time would apply to all providers. Consequently, the proposed ICRs reflect the provider burden associated with complying with and reporting of Stage 3 requirements beginning in 2017 and each subsequent year.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. ICR Regarding Demonstration of Meaningful Use Criteria (§ 495.6, § 495.7 and § 495.8)

In § 495.7 we propose that to successfully demonstrate meaningful use of certified EHR technology for Stage 3, an EP, eligible hospital, or CAH (collectively referred to as ''provider'' in this section) must attest, through a secure mechanism in a specified manner, to the following during the EHR reporting period—

- The provider used certified EHR technology and specified the technology was used; and
- The provider satisfied each of the applicable objectives and associated measures in § 495.7.

In § 495.8, we stipulate that providers must also successfully report the clinical quality measures selected by CMS to CMS or the states, as applicable. We estimate that the certified EHR technology adopted by the provider captures many of the objectives and associated measures and generate automated numerator and denominator information where required, or generate automated summary reports. We also expect that the provider would enable the functionality required to complete the objectives and associated measures that require the provider to attest that they have done so.

We propose that there would be 5 objectives and 10 measures that would require an EP to enter numerators and denominators during attestation. Eligible hospitals and CAHs would have to attest they have met 5 objectives and 10 measures that would require numerators and denominators. For objectives and associated measures requiring a numerator and denominator in this proposed rule, we limit our estimates to actions taken in the presence of certified EHR technology. We do not anticipate a provider would

maintain two recordkeeping systems when certified EHR technology is present. Therefore, we assume that all patient records that would be counted in the denominator would be kept using certified EHR technology. We expect it would take an individual provider or designee approximately 10 minutes to attest to each meaningful use objective and associated measure that requires a numerator and denominator to be generated. The security risk assessment and its associated measure would not require a numerator and denominator and we would expect it would take an individual provider or designee approximately 6 hours to complete. The clinical decision support and active engagement with a public health agency measures would take an eligible professional, eligible hospital or critical access hospital 1 minute each to report each CDS intervention or registry.

We propose that EPs would be required to report on a total of 8 objectives and 16 associated measures. For the purpose of this proposed collection of information, we assumed that all eligible providers would comply with the requirements of meaningful use Stage 3. We propose that eligible hospitals and CAHs would be required to report on a total of 8 objectives and 17 associated measures. We estimated the total annual cost burden for all eligible hospitals and CAHs to attest to EHR technology, meaningful use objectives and associated measures, and electronically submit the clinical quality measures would be $2,135,204 (4,900 eligible hospitals and CAHs × 6 hours 52 minutes × $63.46 (mean hourly rate for lawyers based on May 2013 BLS) data)). We estimate the total annual cost burden for all EPs to attest to EHR technology, meaningful use objectives and associated measures, and electronically submit the clinical quality measures would be $385,834,395 (609,100 EPs × 6 hours 52 minutes × $92.25 (mean hourly rate for physicians based on May 2013 BLS) data).

In this proposed rule, there are 5 objectives that would require an EP to enter numerators and denominators during attestation. Eligible hospitals and CAHs would have to attest that they have met five objectives that require numerators and denominators. For objectives and associated measures requiring a numerator and denominator, we limit our estimates to actions taken in the presence of certified EHR technology. We do not anticipate a provider would maintain two recordkeeping systems when certified EHR technology is present. Therefore, we assume that all patient records that would be counted in the denominator would be kept using certified EHR technology. We expect it would take an individual provider or designee approximately 10 minutes to attest to each meaningful use objective and associated measure that requires a numerator and denominator to be generated, as well as each CQM for providers attesting in their first year of the program.

Additionally, providers would be required to report they have completed objectives and associated measures that require a ''yes'' or ''no'' response during attestation. For EPs, there are three objectives that would require a ''yes'' or ''no'' response during attestation. As discussed previously, the associated measures are that EPs are required to conduct a security risk analysis, report to three registries to fulfil the public health objective, and must implement at least five clinical decision support interventions. For eligible hospitals and CAHs, there are three objectives that would require a ''yes'' or ''no'' response during attestation. The associated measures for eligible hospitals and CAHs require the provider to conduct a security risk analysis, report to four registries to fulfill the public health objective and must implement at least five clinical decision support interventions. We estimate each of these measures would take 1 minute to report.

Providers would also be required to attest that they are protecting electronic health information. We estimate completion of the analysis required to meet successfully the associated measure for this objective would take approximately 6 hours, which is identical to our estimate for the Stage 1 and Stage 2 requirements. This burden estimate assumes that covered entities are already conducting and reviewing these risk analyses under current HIPAA regulations. Therefore, we have not accounted for the additional burden associated with the conduct or review of such analyses.

Table 6 lists those objectives and associated measures for EPs and eligible hospitals and CAHs. We estimate the objectives and associated measures would take an EP 6 hours 52 minutes to complete, and would take an eligible hospital or CAH 6 hours 52 minutes to complete.

In this proposed rule EPs, eligible hospitals, and CAHs have virtually identical burdens. Eligible hospitals and CAHs are required to report to one additional registry than EPs are required to report. Consequently, we have not prepared lowest and highest burdens. Rather, we have computed a burden for EPs and a burden for eligible hospitals and CAHs.

TABLE 6—BURDEN ESTIMATES

Objectives—Eligible professionals	Objectives—Eligible hospitals/CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative and physical safeguards.	Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative and physical safeguards.	Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of data stored in CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.	6 hours	6 hours.
Generate and transmit permissible prescriptions electronically (eRx.).	Generate and transmit permissible discharge prescriptions electronically (eRx).	1. EP Measure: More than 80% of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.	10 minutes	10 minutes.

TABLE 6—BURDEN ESTIMATES—Continued

Objectives—Eligible professionals	Objectives—Eligible hospitals/CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
	.....	2. Eligible Hospital Measure: More than 25% of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.		
Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.	Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.	Measure 1: The EP, eligible hospital and CAH must implement five clinical decision support interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period. Absent four CQMs related to an EP, eligible hospital, or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions.	1 minute	1 minute.
	.....	Measure 2: The EP, eligible hospital, or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.		
Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.	Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.	Measure 1: More than 80 percent of medication orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry..	10 minutes	10 minutes.
	.....	Measure 2: More than 60 percent of laboratory orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry		
	.....	Measure 3: More than 60 percent of diagnostic imaging orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.		
The EP provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability.	The eligible hospital or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability.	Measure 1: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):	10 minutes	10 minutes.
	.....	(1) The patient (or the patient authorized representative) is provided access to view online, download, and transmit his or her health information within 24 hours of its availability to the provider; or		
	.....	(2) The patient (or the patient authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient authorized representatives) access to their health information, within 24 hours of its availability to the provider		

TABLE 6—BURDEN ESTIMATES—Continued

Objectives—Eligible professionals	Objectives—Eligible hospitals/CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
	.....	Measure 2: The EP, eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.		
Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.	Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care	Measure 1: During the EHR reporting period, more than 25 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the electronic health record made accessible by the provider. An EP may meet the measure by either—.	10 minutes	10 minutes.
	.....	(1) More than 25 percent of all unique patients (or patient-authorized representatives) seen by the EP or discharged from the eligible hospital or CAH during the EHR reporting period view, download or transmit to a third party their health information; or		
	.....	(2) More than 25 percent of all unique patients (or patient-authorized representatives) seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period access their health information through the use of an ONC-certified API that can be used by third-party applications or devices.		
	.....	Measure 2: During the EHR reporting period, for more than 35 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient.		
	.....	Measure 3: Patient-generated health data or data from a non-clinical setting is incorporated into the certified EHR technology for more than 15 percent of all unique patients seen by the EP or discharged by the eligible hospital or CAH during the EHR reporting period.		
The EP provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of certified EHR technology.	The eligible hospital or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of certified EHR technology.	Measure 1: For more than 50 percent of transitions of care and referrals, the EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care—(1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.	10 minutes	10 minutes.
	.....	Measure 2: For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, eligible hospital or CAH incorporates into the patient's record in their EHR an electronic summary of care document from a source other than the provider's EHR system.		

TABLE 6—BURDEN ESTIMATES—Continued

Objectives—Eligible professionals	Objectives—Eligible hospitals/CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
	.....	Measure 3: For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, eligible hospital, or CAH performs clinical information reconciliation. The provider would choose at least two of the following three clinical information sets on which to perform reconciliations:		
	.....	*Medication.* Review of the patient's medication, including the name, dosage, frequency, and route of each medication.		
	.....	*Medication allergy.* Review of the patient's known allergic medications.		
	.....	*Current Problem list.* Review of the patient's current and active diagnoses.		
The EP is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.	The eligible hospital or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.	Providers must report data on an ongoing basis to established public health registries.	1 minute	1 minute.
	.....	Measure 1: Immunization Registry Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).		
	.....	Measure 2: Syndromic Surveillance Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care ambulatory setting for EPs, or an emergency or urgent care department for eligible hospitals and CAHs (POS 23).		
	.....	Measure 3: Case Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.		
	.....	Measure 4: Public Health Registry Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit data to public health registries.		
	.....	Measure 5: Clinical Data Registry Reporting: The EP, eligible hospital, or CAH is in active engagement to submit data to a clinical data registry.		
	.....	Measure 6: Electronic Reportable Laboratory Result Reporting: The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results		
	.....	EP Objective: report to 3 of the following registries: Immunization Syndromic Surveillance Case Reporting Public Health Clinical Data		
	.....	EPs may choose to report to more than one public health registry to meet the number of measures required to meet the objective.		
	.....	EPs may choose to report to more than one clinical data registry to meet the number of measures required to meet the objective.		

TABLE 6—BURDEN ESTIMATES—Continued

Objectives—Eligible professionals	Objectives—Eligible hospitals/CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
	.....	EH/CAH Objective: report to 4 of the following registries: Immunization Syndromic Surveillance Case Reporting Public Health Clinical Data Electronic Reportable Laboratory Results.		
	.....	Eligible hospitals and CAHs may choose to report to more than one public health registry to meet the number of measures required to meet the objective.		
	.....	Eligible hospitals and CAHs may choose to report to more than one clinical data registry to meet the number of measures required to meet the objective.		
Criteria Burden Time to Attest and Report Clinical Quality Measures.	.....	.....	6 hours 52 minutes.	6 hours 52 minutes.
Total—Criteria Burden	.....	.....	6 hours 52 minutes.	6 hours 52 minutes.

In this proposed rule, we estimate that it would take no longer than 6 hours and 52 minutes for an EP to satisfy each of the applicable objectives and associated measures. The total burden hours for an EP to attest to the criteria previously specified would be 6 hours 52 minutes. We estimate that there could be approximately 609,100 non-hospital-based Medicare and Medicaid EPs in 2017.

We estimate the burden for the approximately 13,635 MA EPs in the MAO burden section. We estimate the total burden associated with these requirements for an EP would be 6 hours 52 minutes. The total estimated annual cost burden for all EPs to attest to EHR technology and meaningful use objectives would be $385,834,395 (506,400 × 6 hours 52 minutes × $92.25 (mean hourly rate for physicians based on May 2013 BLS data)).

Similarly, eligible hospitals and CAHs would attest that they have met the core meaningful use objectives and associated measures, and would electronically submit the clinical quality measures. We estimate that it would take no longer, than 6 hours and 52 minutes to attest that during the EHR reporting period, they used the certified EHR technology, specify the EHR technology used and satisfied each of the applicable objectives and associated measures. We estimate that there are about 4,900 eligible hospitals and CAHs (3,397 acute care hospitals, 1,395 CAHs, 97 children's hospitals, and 11 cancer hospitals) that may attest to the aforementioned criteria in FY 2017. We estimate the total burden associated with these requirements for an eligible hospital and CAH would be 6 hours 52 minutes. The total estimated annual cost burden for all eligible hospitals and CAHs to attest to EHR technology, meaningful use core set and menu set criteria, and electronically submit the clinical quality measures would be $2,135,204 (4,908 eligible hospitals and CAHs × $63.46 (6 hours 52 minutes × $63.46 (mean hourly rate for lawyers based on May 2013 BLS) data)).

B. ICRs Regarding Qualifying MA Organizations (§ 495.210)

In this proposed rule, we estimate that the burden would be significantly less for qualifying MA organizations attesting to the meaningful use of their MA EPs in Stage 3, because qualifying MA EPs use the EHR technology in place at a given location or system, so if certified EHR technology is in place and the qualifying MA organization requires its qualifying MA EPs to use the technology, qualifying MA organizations would be able to determine at a faster rate than individual FFS EPs, that its qualifying MA EPs meaningfully used certified EHR technology. In other words, qualifying MA organizations can make the determination together if the certified EHR technology is required to be used at its facilities, whereas under FFS, each EP likely must make the determination on an individual basis. We estimate that, on average, it would take an individual 45 minutes to collect information necessary to determine if a given qualifying MA EP has met the meaningful use objectives and measures, and 15 minutes for an individual to make the attestation for each MA EP. Furthermore, the individuals performing the assessment and attesting would not likely be eligible professional, but non-clinical staff. We believe that the individual gathering the information could be equivalent to a GS 11, step 1 (2015 unadjusted for locality rate), with an hourly rate of approximately $25.00/hour, and the person attesting (and who may bind the qualifying MA organization based on the attestation) could be equivalent to a GS 15, step 1 (2015 unadjusted for locality rate), or approximately $50.00/hour. Therefore, for the estimated 13,635 potentially qualifying MA EPs, we believe it would cost the participating qualifying MA organizations approximately $426,050 annually to make the attestations ([10,226 hours × $25.00] + [3,408 hours × $50.00]).

C. ICR Regarding State Reporting Requirements (§ 495.316 and § 495.352)

We are proposing to revise 42 CFR 495 regarding state reporting requirements to CMS. With respect to the annual reporting requirements in § 495.316 and the quarterly reporting requirements in § 495.352, we do not believe that the proposed amendments to these reporting requirements would increase the burden on states beyond what was previously finalized under OMB control number 0938–1158 following the Stage 2 final rule. The

deadlines we propose or are considering would be consistent with our past practice, and the changes we propose or consider to the data elements to be reported on would be either reduced or similar in burden. Similarly, we do not expect the proposed amendments regarding the 90-day EHR reporting period for first time meaningful users would impose a burden on states because those amendments would generally maintain the current policy.

However, we are proposing to revise § 495.316 to include a new quarterly reporting requirement. Under the proposed amendment, states would report quarterly to CMS regarding the EPs and Medicaid eligible hospitals that have successfully demonstrated meaningful use for each payment year. We need this information to ensure that those EPs who are meaningful EHR users in the Medicaid EHR Incentive Program are appropriately exempted from the Medicare payment adjustment. We cannot accurately exempt these providers using the current data received from states. We expect that it would take a state 20 hours each year to submit this report on a quarterly basis. We believe that the state employee reporting the information could be equivalent to a GS 12, step 1 (2015 unadjusted for locality rate), with an hourly rate of approximately $30.00/hour. This amount is then reduced by the 90 percent federal contribution for administrative services for Medicaid under the EHR Incentive Programs, this equates to approximately $3.00/hour. Therefore, for all state Medicaid agencies to report four times per year at 20 hours per report the estimated cost is $13,460 (4560 hours × $3.00/hour).

TABLE 7—ESTIMATED ANNUAL INFORMATION COLLECTION BURDEN

Reg section	OMB Control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total cost ($)
§ 495.x—Objectives/Measures (EPs)	0938–1158	609,100	609,100	6.86	4,178,426	92.25	385,834,395
§ 495.6—Objectives/Measures (hospitals/CAHs)	0938–1158	4,900	4,900	6.86	33,614	63.46	2,135,204
§ 495.210—Gather information for attestation (MA EPs)	0938–1158	13,635	13,635	0.75	10,226	25.00	255,650
§ 495.210—Attestation on behalf of MA EPs	0938–1158	13,635	13,635	0.25	3408.75	50.00	170,400
§ 495.316—Quarterly Reporting	0938–1158	56	224	20	4480	3.00	13,440
Totals		627,635	627,635		4,225,674		388,408,189

Notes:
All non-whole numbers in this table are rounded to 2 decimal places.
There are no capital/maintenance costs associated with the information collection requirements contained in this rule. Therefore, we have removed the associated column from Table 7.

If you would like to comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this final rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS–3310–P], Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov.*

IV. 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 proposed rule, and when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

This proposed rule would implement the provisions of the ARRA that provide incentive payments to EPs, eligible hospitals, and CAHs participating in Medicare and Medicaid programs that adopt and meaningfully use certified EHR technology. This proposed rule specifies applicable criteria for demonstrating Stage 3 of meaningful use.

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 Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This proposed rule is anticipated to have an annual effect on the economy of $100 million or more, making it an economically significant rule under the Executive Order and a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis (RIA) that presents the estimated costs and benefits of this proposed rule.

As noted in section I.A.2. of this proposed rule, this proposed rule is one of two coordinated rules related to the

meaningful use of certified EHR technology. The other is ONC's 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications proposed elsewhere in this issue of the **Federal Register**. This analysis focuses on the impact associated with Stage 3 requirements for meaningful use, the changes in quality measures that would take effect beginning in 2017, and other changes being proposed for the Medicare and Medicaid EHR Incentive Programs.

As we discussed in the Stage 2 final rule (77 FR 54163 through 54291), a number of factors would affect the adoption of EHR systems and demonstration of meaningful use. In this proposed rule, we continue to believe that a number of factors would affect the adoption of EHR systems and demonstration of meaningful use. Readers should understand that these forecasts are also subject to substantial uncertainty since demonstration of meaningful use will depend not only on the standards and requirements for 2017 and for eligible hospitals and EPs, but on future rulemakings issued by the HHS.

We further stated in the 2012 Stage 2 final rule (77 FR 54135 through 54136), the statute provides Medicare and Medicaid incentive payments for the meaningful use of certified EHR technology. Additionally, the Medicaid program also provides incentives for the adoption, implementation, and upgrade of certified EHR technology. Beginning in 2015, payment adjustments are incorporated into the Medicare EHR Incentive Program for providers unable to demonstrate meaningful use. The absolute and relative strength of these is unclear. For example, a provider with relatively small Medicare billings will be less disadvantaged by payment adjustments than one with relatively large Medicare billings. Another uncertainty arises because there are likely to be ''bandwagon'' effects as the number of providers using EHRs rises, thereby inducing more participation in the incentives program, as well as greater adoption by entities (for example, clinical laboratories) that are not eligible for incentives or subject to payment adjustments, but do business with EHR adopters. It is impossible to predict exactly if and when such effects may take hold.

An uncertainty arises because under current law, physicians are scheduled for a large payment reduction in April 2015 under the sustainable growth rate (SGR) formula, which determines Medicare physician payment updates. A large payment reduction could cause major changes in physician behavior, enrollee care, and other Medicare provider payments, but the specific nature of these changes is uncertain. Under current law, the remaining EHR incentives for Medicaid or the Medicaid payment adjustments will exert only a minor influence on physician behavior relative to this large physician payment reduction. However, the Congress has legislatively avoided a large physician payment reduction for each year since 2002.

All of these factors taken together make it impossible in this proposed rule to predict with precision the timing or rates of adoption and meaningful use. However, new data is currently available regarding rates of adoption or costs of implementation since the publication of our Stage 1 and Stage 2 final rules. We have included the new data in our estimates, although even these forecasts are still fairly uncertain.

Overall, in this proposed rule, we expect spending under the EHR incentive program for transfer payments to Medicare and Medicaid providers between 2017 and 2020 to be $3.7 billion (this estimate includes net payment adjustments for Medicare providers who do not achieve meaningful use in the amount of $0.8 billion). We have also estimated ''per entity'' costs for EPs, eligible hospitals, and CAHs for implementation/maintenance and reporting requirement costs, not all costs. We believe many adopting entities may achieve dollar savings at least equal to their total costs, and that there may be additional benefits to society. We also believe that implementation costs are significant for each participating entity because providers who were like to qualify as meaningful users of EHRs were likely to purchase certified EHR technology. However, we believe that providers who have already purchased certified EHR technology and participated in Stage 1 or Stage 2 of meaningful use will experience significantly lower costs for participation in the program. We continue to believe that the short-term costs to demonstrate meaningful use of certified EHR technology may be outweighed by the long-term benefits, including practice efficiencies and improvements in medical outcomes. Although both cost and benefit estimates are highly uncertain, the RIA that we have prepared presents the estimated costs and benefits of this proposed rule.

C. Anticipated Effects

The objective of the remainder of this proposed RIA is to summarize the costs and benefits of the HITECH Act incentive program for the Medicare FFS, Medicaid, and MA programs. We also provide assumptions and a narrative addressing the potential costs to the health care industry for implementation of this technology.

1. Overall Effects

a. EHR Technology Development and Certification Costs

We note that the costs incurred by IT developers for EHR technology development and certification to the 2015 Edition certification criteria for health IT are also in part attributable to the requirements for the use of CEHRT established in this proposed rule for Stage 3 of the EHR Incentive Programs. Therefore, to the extent that providers' implementation and adoption costs are attributable to this proposed rule, health IT developers' preparation and development costs would also be attributable as these categories of activities may be directly or indirectly incentivized by the requirements to demonstrate meaningful use. However, even if this Stage 3 proposed rule were not finalized, other CMS programs (for example PQRS and IQR) do require or promote certification to ONC's criteria—or a professional organization or other such entity could require or promote certification to ONC's critieria.[13] As noted previously, this analysis focuses on the impact associated with Stage 3 requirements for meaningful use for providers; while the development and certification costs are addressed in the the 2015 Edition proposed rule published elsewhere in this issues of the **Federal Register**.

b. Regulatory Flexibility Analysis and Small Entities

The Regulatory Flexibility Act (RFA) requires agencies to prepare an Initial Regulatory Flexibility Analysis to describe and analyze the impact of the proposed rule on small entities unless the Secretary can certify that the regulation will not have a significant impact on a substantial number of small entities. In the health care sector, Small Business Administration (SBA) size standards define a small entity as one with between $7 million and $34 million in annual revenues. For the purposes of the RFA, essentially all non-profit organizations are considered small entities, regardless of size.

[13] In this case, the provider implementation and adoption costs discussed in this CMS RIA would instead be attributable to ONC's rulemaking.

Individuals and states are not included in the definition of a small entity. Since the vast majority of Medicare providers (well over 90 percent) are small entities within the RFA's definitions, it is the normal practice of HHS simply to assume that all affected providers are ''small'' under the RFA. In this case, most EPs, eligible hospitals, and CAHs are either nonprofit or meet the SBA's size standard for small business. We also believe that the effects of the incentives program on many and probably most of these affected entities would be economically significant. Accordingly, this RIA section, in conjunction with the remainder of the preamble, constitutes the required Initial Regulatory Flexibility Analysis (IRFA). We believe that the adoption and meaningful use of EHRs will have an impact on virtually every EP and eligible hospital, as well as CAHs and some EPs and hospitals affiliated with MA organizations. While the program is voluntary, in the first 5 years it carries substantial positive incentives that make it attractive to virtually all eligible entities. Furthermore, entities that do not demonstrate meaningful use of EHR technology for an applicable reporting period will be subject to significant Medicare payment reductions beginning in 2015. These Medicare payment adjustments are expected to motivate EPs, eligible hospitals, and CAHs to adopt and meaningfully use certified EHR technology.

For some EPs, CAHs, and eligible hospitals the EHR technology currently implemented could be upgraded to meet the criteria for certified EHR technology as defined for this program. These costs may be minimal, involving no more than a software upgrade. ''Home-grown'' EHR systems that might exist may also require an upgrade to meet the certification requirements. We believe many currently used non-certified EHR systems will require significant changes to achieve certification and that EPs, CAHs, and eligible hospitals will have to make process changes to achieve meaningful use.

Data available suggests that more providers have adopted EHR technology since the publication of the Stage 1 final rule. An ONC data brief (No. 16, May 2014) noted that hospital adoption of EHR systems has increased 5 fold since 2008. Nine in ten acute care hospitals possessed CEHRT in 2013, increasing 29 percent since 2011. In January 2014, a Centers for Disease Control and Prevention (CDC) data brief entitled, ''Use and Characteristics of Electronic Health Record Systems Among Office-based Physician Practices: United States, 2001 through 2013 found that 78 percent of office-based used any type of EHR systems, up from 18 percent in 2001. The majority of EPs have already purchased certified EHR technology, implemented this new technology, and trained their staff on its use. The costs for implementation and complying with the criteria of meaningful use could lead to higher operational expenses. However, we believe that the combination of payment incentives and long-term overall gains in efficiency may compensate for some of the initial expenditures.

(1) Small Entities

We estimate that EPs would spend approximately $54,000 to purchase and implement a certified EHR and $10,000 annually for ongoing maintenance according to the Congressional Budget Office (CBO) (75 FR 44546).

In the paper, Evidence on the Costs and Benefits of Health Information Technology, May 2008, in attempting to estimate the total cost of implementing health IT systems in office-based medical practices, recognized the complicating factors of EHR types, available features and differences in characteristics of the practices that are adopting them. The CBO estimated a cost range of $25,000 to $45,000 per physician. Annual operating and maintenance amount was estimated at 12 to 20 percent of initial costs (that is, $3,000 to $9,000) per physician. For all eligible hospitals, the range is from $1 million to $100 million. Though reports vary widely, we anticipate that the average will be $5 million for eligible hospitals to achieve meaningful use. We estimate $1 million for maintenance, upgrades, and training each year per eligible hospital. However, as stated earlier many providers have already purchased systems with expenditures focused on maintenance and upgrades. We believe that future retrospective studies on the costs to implement and EHR and the return on investment (ROI) will demonstrate the actual costs incurred by providers participating in the EHR Incentive Programs.

(2) Conclusion

As discussed later in this analysis, we believe that there are many positive effects of adopting EHR on health care providers. We believe that the net effect on some individual providers may be positive. Accordingly, we believe that the object of the RFA to minimize burden on small entities is met by this proposed rule.

b. Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis (RIA) if a rule will 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 of a metropolitan statistical area and has fewer than 100 beds. This proposed rule would affect the operations of a substantial number of small rural hospitals because they may be subject to adjusted Medicare payments in 2015 if they fail to adopt certified EHR technology by the applicable reporting period. As stated previously, we have determined that this proposed rule would create a significant impact on a substantial number of small entities, and have prepared a Regulatory Flexibility Analysis as required by the RFA and, for small rural hospitals, section 1102(b) of the Act. Furthermore, any impacts that would arise from the implementation of certified EHR technology in a rural eligible hospital would be positive, with respect to the streamlining of care and the ease of sharing information with other EPs to avoid delays, duplication, or errors. However, the Secretary retains the discretionary statutory authority to make case-by-case exceptions for significant hardships, and has already established certain categories where case-by-case applications may be made such as barriers to internet connectivity that impact health information exchange.

c. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates will require spending in any 1 year $100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately $141 million. UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those ''federal mandate'' costs resulting from—(1) imposing enforceable duties on state, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, state, local, or tribal governments under entitlement programs.

This proposed rule imposes no substantial mandates on states. This program is voluntary for states and states offer the incentives at their option. The state role in the incentive program is essentially to administer the Medicaid incentive program. While this entails certain procedural responsibilities, these do not involve

substantial state expense. In general, each state Medicaid Agency that participates in the incentive program would be required to invest in systems and technology to comply. States would have to identify and educate providers, evaluate their attestations and pay the incentive. However, the federal government would fund 90 percent of the state's related administrative costs, providing controls on the total state outlay.

The investments needed to meet the meaningful use standards and obtain incentive funding are voluntary, and hence not ''mandates'' within the meaning of the statute. However, the potential reductions in Medicare reimbursement beginning with FY 2015 would have a negative impact on providers that fail to meaningfully use certified EHR technology for the applicable reporting period. We note that we have no discretion as to the amount of those potential payment reductions. Private sector EPs that voluntarily choose not to participate in the program may anticipate potential costs in the aggregate that may exceed $141 million. However, because EPs may choose for various reasons not to participate in the program, we do not have firm data for the percentage of participation within the private sector. This RIA, taken together with the remainder of the preamble, constitutes the analysis required by UMRA.

d. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This proposed rule will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have a federalism implication. Importantly, state Medicaid agencies are receiving 100 percent match from the federal government for incentives paid and a 90-percent match for expenses associated with administering the program. As previously stated, we believe that state administrative costs are minimal. We note that this proposed rule does add a new business requirement for states, because of the existing systems that would need to be modified to track and report on the new meaningful use requirements for provider attestations. We are providing 90-percent FFP to states for modifying their existing EHR Incentive Program systems. We believe the federal share of the 90-percent match will protect the states from burdensome financial outlays and as noted previously, states offer the Medicaid EHR incentive program at their option.

2. Effects on EPs, Eligible Hospitals, and CAHs

a. Background and Assumptions

The principal costs of this proposed rule are the additional expenditures that will be undertaken by eligible entities in order to obtain the Medicare and Medicaid incentive payments to adopt, implement or upgrade and/or demonstrate meaningful use of certified EHR technology, and to avoid the Medicare payment adjustments that will ensue if they fail to do so. The estimates for the provisions affecting Medicare and Medicaid EPs, eligible hospitals, and CAHs are somewhat uncertain for several reasons: (1) The program is voluntary although payment adjustments will be imposed on Medicare providers beginning in 2015 if they are unable to demonstrate meaningful use for the applicable reporting period; (2) the criteria for the demonstration of meaningful use of certified EHR technology has been finalized for Stage 1 and Stage 2 and is being proposed for Stage 3, but may change over time; and (3) the impact of the financial incentives and payment adjustments on the rate of adoption of certified EHR technology by EPs, eligible hospitals, and CAHs is difficult to predict based on the information we have currently collected. The net costs and savings shown for this program represent a possible scenario and actual impacts could differ substantially.

Based on input from a number of internal and external sources, we estimated the numbers of EPs and eligible hospitals, including CAHs under Medicare, Medicaid, and MA and used them throughout the analysis.

- About 675,500 Medicare FFS EPs in 2017 (some of whom will also be Medicaid EPs).
- About 60,600 non-Medicare eligible EPs (such as dentists, pediatricians, and eligible non-physicians such as certified nurse-midwives, nurse practitioners, and physicians assistants) could be eligible to receive the Medicaid incentive payments in 2017.
- 4,900 eligible hospitals comprising the following:

++ 3,397 acute care hospitals

++ 1,395 CAHs

++ 97 children's hospitals (Medicaid only)

++ 11 cancer hospitals (Medicaid only)

- All eligible hospitals, except for children's and cancer hospitals, may qualify and apply for both Medicare and Medicaid incentive payments.
- About 16 MA organizations

b. Industry Costs and Adoption Rates

In the Stage 2 final rule (77 FR 54136 through 54146), we estimated the impact on health care providers using information from four studies. In the absence of any more recent estimates that we are aware of, in this proposed rule, we continue to use the same estimates cited in the Stage 2 final rule. We continue to believe that these estimates are reasonably reflective of EHR costs. However, we note, we are unable to delineate all costs due to the great variability in characteristics among the entities that are affected by the proposed rule; the variability includes, but is not limited to, the size of the practice, extent of use of electronic systems, type of system used, number of staff using the EHR system and the cost for maintaining and/or upgrading systems. Based on these studies and current average costs for available certified EHR technology products, we continue to estimate for EPs that the average adopt/implement/upgrade cost is $54,000 per physician FTE, while annual maintenance costs average $10,000 per physician FTE.

For all eligible hospitals, we continue to estimate the range is from $1 million to $100 million. Although reports vary widely, we continue to anticipate that the average will be $5 million to achieve meaningful use, because providers who will like to qualify as meaningful users of EHRs will need to purchase certified EHRs. We further acknowledge ''certified EHRs'' may differ in many important respects from the EHRs currently in use and may differ in the functionalities they contain. We continue to estimate $1 million for maintenance, upgrades, and training each year. Both of these estimates are based on average figures provided in the 2008 CBO report. However, as noted previously, we are unable to delineate all costs due to the great variability in characteristics among the entities that are affected by the proposed rule; the variability includes, but is not limited to, the size of the hospital, extent of use of electronic systems, type of system used, number of staff using the EHR system and the cost for maintaining and/or upgrading systems.

Industry costs are important, in part, because EHR adoption rates will be a function of these industry costs and the extent to which the costs of ''certified EHRs'' are higher than the total value of EHR incentive payments available to EPs and eligible hospitals (as well as adjustments, in the case of the Medicare

EHR incentive program) and any perceived benefits including societal benefits. Because of the uncertainties surrounding industry cost estimates, we have made various assumptions about adoption rates in the following analysis in order to estimate the budgetary impact on the Medicare and Medicaid programs.

c. Costs of EHR Adoption for EPs

Since the publication of the Stage 1 final rule, there has been little data published regarding the cost of EHR adoption and implementation. A 2011 study (*http://content.healthaffairs.org/content/30/3/481.abstract*) estimated costs of implementation for a five-physician practice to be $162,000, with $85,500 in maintenance expenses in the first year. In the absence of additional data regarding the cost of adoption and implementation costs for certified EHR technology, we proposed to continue to estimate for EPs that the average adopt/implement/upgrade cost is $54,000 per physician FTE, while annual maintenance costs average $10,000 per physician FTE, based on the cost estimate of the Stage 1 final rule. However, as noted previously, we are unable to delineate all costs due to the great variability that are affected by but not limited to the size of the practice, extent of use of electronic systems, type of system used, number of staff using the EHR system, and the cost for maintaining and/or upgrading systems.

d. Costs of EHR Adoption for Eligible Hospitals

According to the American Hospital Association 2008 Survey, the range in yearly information technology spending among hospitals ranged from $36,000 to over $32 million. EHR system costs specifically were reported by other experts to run as high as $20 million to $100 million (77 FR 54139). We note that recently we have seen about 96 percent of eligible hospitals have received at least one incentive payment under either the Medicare or Medicaid programs. However, as noted previously, we are unable to delineate all costs due to the great variability that are affected by but not limited to the size of the eligible hospital, extent of use of electronic systems, type of system used, number of staff using the EHR system, and the cost for maintaining and/or upgrading systems.

3. Medicare Incentive Program Costs

The estimates for the HITECH Act provisions are based on the economic assumptions underlying the President's FY 2016 Budget. Under the statute, Medicare incentive payments for certified EHR technology are excluded from the determination of MA capitation benchmarks. We continue to expect a negligible impact on benefit payments to hospitals and EPs from Medicare and Medicaid because of the implementation of EHR technology.

As noted at the beginning of this analysis, it is difficult to predict the actual impacts of the HITECH Act with great certainty. We believe the assumptions and methods described herein are reasonable for estimating the financial impact of the provisions on the Medicare and Medicaid programs, but acknowledge the wide range of possible outcomes.

a. Medicare Eligible Professionals (EPs)

We began making EHR Incentive payments in 2011. Medicare payments are to be paid for the successful demonstration on meaningful use through CY 2016. Due to the payment lag, some payments may be issued in CY 2017. To avoid the Medicare payment adjustment beginning in 2015, EPs need to successfully demonstrate meaningful use regardless of whether they earn an incentive payment. We estimated the percentage of the remaining EPs who would be meaningful users each calendar year. Table 8 shows the results of these calculations.

TABLE 8—MEDICARE EPS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY

	Calendar year			
	2017	2018	2019	2020
Medicare EPs who have claims with Medicare (thousands)	675.5	683.3	691.1	698.8
Non-Hospital-based Medicare EPs (thousands)	609.1	616.1	623.1	630.1
Percent of EPs who are Meaningful Users	70	73	75	78
Meaningful Users (thousands)	426.4	446.7	467.3	488.3

Our estimates of the incentive payment costs and payment adjustment savings are presented in Table 9. They reflect actual historical data and our assumptions about the proportion of EPs who will demonstrate meaningful use of certified EHR technology. Estimated costs are expected to decrease in 2017 through 2020 due to a smaller number of new EPs that would achieve meaningful use and the cessation of the incentive payment program. Payment adjustment receipts represent the estimated amount of money collected due to the payment adjustments for those not achieving meaningful use. Estimated net costs for the Medicare EP portion of the HITECH Act are also shown in Table 9.

TABLE 9—ESTIMATED COSTS (+) AND SAVINGS (−) FOR MEDICARE EPS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY

[In Billions]

Fiscal Year	Incentive payments	Payment adjustment receipts	Benefit payments	Net total
2017	$0.6	−$0.2	—	$0.3
2018	—	−0.2	—	−0.2
2019	—	−0.2	—	−0.2
2020	—	−0.1	—	−0.1

b. Medicare Eligible Hospitals and CAHs

In brief, the estimates of hospital adoption were developed by calculating projected incentive payments and then making assumptions about how rapidly hospitals would adopt meaningful use.

Specifically, the first step in preparing estimates of Medicare program costs for eligible hospitals was to determine how many eligible hospitals already received payments under the EHR Incentive program and for what years those payments were received. In order to do this, we used the most recent available data that listed the recipients of incentive payments, and the year and payment amount. This information pertained to eligible hospitals receiving payments through September 2014.

We assume that all eligible hospitals that receive a payment in the first year will receive payments in future years. We also assume the eligible hospitals that have not yet received any incentive payments will eventually achieve meaningful use (either to receive incentive payments or to avoid payment adjustments). We assume that all eligible hospitals would achieve meaningful use by 2018. No new incentive payments would be paid after 2016. However, some incentive payments originating in 2016 would be paid in 2017.

The average incentive payment for each eligible hospital was $1.5 million in the first year. In later years, the amount of the incentive payments drops according to the schedule allowed in law. The average incentive payment for CAHs received in the first year was about $950,000. The average incentive payment received in the second year was about $332,500. The average incentive payment received in the third year was about $475,000. These average amounts were used for these incentive payments in the future. The third year average was also used for the fourth year. These assumptions about the number of hospitals achieving meaningful use in a particular year and the average amount of an incentive payment allows us to calculate the total amount of incentive payments to be made and the amount of payment adjustments for those hospitals who have not achieved meaningful use. The payment incentives available to hospitals under the Medicare and Medicaid EHR Incentive Programs are included in our regulations at 42 CFR part 495. We further estimate that there are 16 MA organizations that might be eligible to participate in the incentive program. Those plans have 32 eligible hospitals. The costs for the MA program have been included in the overall Medicare estimates.

The estimated payments to eligible hospitals were calculated based on the hospitals' qualifying status and individual incentive amounts under the statutory formula. Similarly, the estimated payment adjustments for non-qualifying hospitals were based on the market basket reductions and Medicare revenues. The estimated savings in Medicare eligible hospital benefit expenditures resulting from the use of hospital certified EHR systems were discussed earlier in this section. We assumed no future growth in the total number of hospitals in the U.S. because growth in acute care hospitals has been minimal in recent years. The results are shown in Table 10.

TABLE 10—ESTIMATED COSTS (+) AND SAVINGS (−) FOR MEDICARE ELIGIBLE HOSPITALS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY

[In billions]

Fiscal year	Incentive payments	Payment adjustment receipts	Benefit payments	Net total
2017	$1.6	(1)	(1)	$1.6
2018	0.0	(1)	(1)	(1)
2019	0.0	0.0	(1)	(1)
2020	0.0	0.0	(1)	(1)

[1] Savings of less than $50 million. All numbers are projections.

4. Medicaid Incentive Program Costs

Under section, 4201 of the HITECH Act, states and territories can voluntarily participate in the Medicaid EHR Incentive Program. However, as of the writing of this proposed rule, all states already participate. The payment incentives available to EPs and eligible hospitals under the Medicaid EHR Incentive Program are included in our regulations at 42 CFR part 495. The federal costs for Medicaid incentive payments to providers who can demonstrate meaningful use of EHR technology were estimated similarly to the estimates for Medicare eligible hospitals and EPs. Table 11 shows our estimates for the net Medicaid costs for eligible hospitals and EPs.

TABLE 11—ESTIMATED FEDERAL COSTS (+) AND SAVINGS (−) UNDER MEDICAID

[In $billions]

Fiscal year	Incentive payments		Benefit payments	Net total
	Hospitals	Eligible professionals		
2017	0.4	0.8	(1)	1.2
2018	0.1	0.5	(1)	0.6
2019	0	0.3	(1)	0.3
2020	0.0	0.2	(1)	0.2

[1] Savings of less than $50 million.

a. Medicaid EPs

TABLE 12—ASSUMED NUMBER OF NONHOSPITAL BASED MEDICAID EPS WHO WOULD BE MEANINGFUL USERS OF CERTIFIED EHR TECHNOLOGY

[Population figures in thousands]

		Calendar year			
		2017	2018	2019	2020
A	EPs who meet the Medicaid patient volume threshold	101.3	102.3	103.3	104.4
B	Medicaid only Eps	60.6	61.7	62.9	64.0
	Total Medicaid EPs (A + B)	161.8	164.0	166.2	168.4
	Percent of EPs receiving incentive payment during year	44.7%	30.9%	20.7%	14.3%
	Number of EPs receiving incentive payment during year	72.4	50.7	34.5	24.0
	Percent of EPs who have ever received incentive payment	67.9%	74.7%	78.0%	81.1%
	Number of EPs who have ever received incentive payment	109.9	122.5	129.6	136.6

It should be noted that since the Medicaid EHR Incentive Program provides that a Medicaid EP can receive an incentive payment in his or her first year because he or she has demonstrated a meaningful use or because he or she has adopted, implemented, or upgraded certified EHR technology, these participation rates include not only meaningful users but eligible providers implementing certified EHR technology as well.

b. Medicaid Hospitals

Medicaid incentive payments to most eligible hospitals were estimated using the same methodology as described previously for Medicare eligible hospitals and shown in Table 10. Many eligible hospitals may qualify to receive both the Medicare and Medicaid incentive payment. We assume that all eligible hospitals would achieve meaningful use by 2016. However, many of these eligible hospitals would have already received the maximum amount of incentive payments. Table 13 shows our assumptions about the remaining incentive payments to be paid.

TABLE 13—ESTIMATED PERCENTAGE OF HOSPITALS THAT COULD BE PAID FOR MEANINGFUL USE AND ESTIMATED PERCENTAGE PAYABLE IN YEAR

Fiscal year	Percent of hospitals who are meaningful users	Percent of hospitals being paid
2017	100.0	13.5
2018	100.0	5.2
2019	100.0	1.5
2020	100.0	0.0

As stated previously, the estimated eligible hospital incentive payments were calculated based on the eligible hospitals' qualifying status and individual incentive amounts payable under the statutory formula. The average Medicaid incentive payment in the first year was $1 million. The estimated savings in Medicaid benefit expenditures resulting from the use of certified EHR technology are discussed in section V.C.4. of this proposed rule. Since we use Medicare data and little data existed for children's hospitals, we estimated the Medicaid incentives payable to children's hospitals as an add-on to the base estimate, using data on the number of children's hospitals compared to non-children's hospitals.

5. Benefits for all EPs and all Eligible Hospitals

In this proposed rule, we have not quantified the overall benefits to the industry, nor to eligible hospitals or EPs in the Medicare, Medicaid, or MA programs. Although information on the costs and benefits of adopting systems that specifically meet the requirements for the EHR Incentive Programs (for example, certified EHR technology) has not yet been collected, and although some studies question the benefits of health information technology, a 2011 study completed by ONC (Buntin et al. 2011 ''The Benefits of Health Information Technology: A Review of the Recent Literature Shows Predominantly Positive Results'' Health Affairs.) found that 92 percent of articles published from July 2007 up to February 2010 reached conclusions that showed the overall positive effects of health information technology on key aspects of care, including quality and efficiency of health care. Among the positive results highlighted in these articles were decreases in patient mortality, reductions in staffing needs, correlation of clinical decision support to reduced transfusion and costs, reduction in complications for patients in hospitals with more advanced health IT, and a reduction in costs for hospitals with less advanced health IT. A subsequent 2013 study completed by the RAND Corporation for ONC (Shekelle et al. 2013 ''Health Information Technology: An Updated Systemic Review with a Focus on Meaningful Use Functionalities'') found 77 percent of articles published between January 2010 to August 2013 that evaluated the effects of health IT on healthcare quality, safety, and efficiency reported findings that were at least partially positive. The Centers for Disease Control and Prevention publication in January 2014, (Hsiao et al, ''Use and Characteristics of Electronic Health Record Systems Among Office-based Physician Practices: United states, 2001–2013'') concluded that the adoption of basic EHR systems by office-based physicians increased 21 percent between 2012 and 2013, varying widely across the states ranging from 21 percent in New Jersey to 83 percent in North Dakota. Another study, at one hospital emergency room in Delaware, showed the ability to download and create a file with a patient's medical history saved the ER $545 per use, mostly in reduced waiting times. A pilot study of ambulatory practices found a positive ROI within 16 months and annual savings thereafter (Greiger et al. 2007, A Pilot Study to Document the Return on Investment for Implementing an Ambulatory Electronic Health Record at an Academic Medical Center *http://www.journalacs.org/article/S1072-;7515%2807%2900390-0/abstract-article-footnote-1*.) Another study compared the productivity of 75 providers within a large urban primary care practice over a 4-year period showed increases in productivity of 1.7 percent per month per provider after EHR adoption (DeLeon et al. 2010, ''The business end of health information technology''). Some vendors have estimated that EHRs could result in cost savings of between $100 and $200 per patient per year. As participation and adoption increases, there will be more opportunities to capture and report on cost savings and benefits.

6. Benefits to Society

According to the CBO study ''Evidence on the Costs and Benefits of Health Information Technology'' (*http://www.cbo.gov//ftpdocs/91xx/doc9168/05-20-HealthIT.pdf*) when used effectively, EHRs can enable providers to deliver health care more efficiently. For example, the study states that EHRs can reduce the duplication of diagnostic tests, prompt providers to prescribe cost-effective generic medications, remind patients about preventive care, reduce unnecessary office visits, and assist in managing complex care. This is consistent with the findings in the ONC study cited previously. Further, the CBO report claims that there is a potential to gain both internal and external savings from widespread adoption of health IT, noting that internal savings will likely be in the reductions in the cost of providing care, and that external savings could accrue to the health insurance plan or even the patient, such as the ability to exchange information more efficiently. However, it is important to note that the CBO identifies the highest gains accruing to large provider systems and groups and claims that office-based physicians may not realize similar benefits from purchasing health IT products. At this time, there is limited data regarding the efficacy of health IT for smaller practices and groups, and the CBO report notes that this is a potential area of research and analysis that remains unexamined. The benefits resulting specifically from this proposed rule are even harder to quantify because they represent, in many cases, adding functionality to existing systems and reaping the network externalities created by larger numbers of providers participating in information exchange.

In the Stage 2 final rule at 77 FR 54144, we discussed research documenting the association of EHRs with improved outcomes among diabetics (Hunt, JS et al. (2009) ''The impact of a physician-directed health information technology system on diabetes outcomes in primary care: A pre- and post-implementation study'' Informatics in Primary Care 17(3): 165-74; Pollard, C et al. (2009) ''Electronic patient registries improve diabetes care and clinical outcomes in rural community health centers'' Journal of Rural Health 25(1): 77-84) and trauma patients (Deckelbaum, D. et al. (2009) ''Electronic medical records and mortality in trauma patients ''The Journal of Trauma: Injury, Infection, and Critical Care 67(3): 634-636), enhanced efficiencies in ambulatory care settings (Chen, C et al. (2009) ''The Kaiser Permanente Electronic Health Record: Transforming and Streamlining Modalities Of Care. ''Health Affairs'' 28(2): 323-333), and improved outcomes and lower costs in hospitals (Amarasingham, R. et al. (2009) ''Clinical information technologies and inpatient outcomes: A multiple hospital study'' Archives of Internal Medicine 169(2): 108-14). The 2013 ONC report cited previously reported findings from their literature review on health IT and safety of care, health IT and quality of care, health IT and safety of care, and health It and efficiency of care in ambulatory and non-ambulatory care settings. The report indicated that a majority of studies that evaluated the effects of health IT on healthcare quality, safety, and efficiency reported findings that were at least partially positive. The report concluded that their findings ''suggested that health IT, particularly those functionalities included in the Meaningful Use . . ., can improve healthcare quality and safety.'' However, data relating specifically to the EHR Incentive Programs is limited at this time.

7. Summary

In this proposed rule, the total cost to the Medicare and Medicaid programs between 2017 and 2020 is estimated to be $3.7 billion in transfers. As discussed in section V.C.4. of this proposed rule, we do not estimate total costs to the provider industry, but rather provide a possible per EP and per eligible hospital outlay for implementation and maintenance.

TABLE 14—ESTIMATED EHR INCENTIVE PAYMENTS AND BENEFITS IMPACTS ON THE MEDICARE AND MEDICAID PROGRAMS OF THE HITECH EHR INCENTIVE PROGRAM (FISCAL YEAR)

[In billions]

Fiscal year	Medicare eligible		Medicaid eligible		Total
	Hospitals	Professionals	Hospitals	Professionals	
2017	$1.6	$0.3	$0.4	$0.8	$3.1
2018	0.0	−0.2	0.1	0.5	0.4
2019	0.0	−0.2	0.0	0.3	0.1
2020	0.0	−0.1	0.0	0.2	0.1
Total	1.6	−0.2	0.5	1.8	3.7

D. Alternatives Considered

As stated in the Stage 1 final rule (75 FR 44546), HHS has no discretion to change the incentive payments or payment adjustment reductions specified in the statute for providers that adopt or fail to adopt a certified EHR and demonstrate meaningful use of certified EHR technology. However, we have discretion around how best to meet the HITECH Act requirements for meaningful use for FY 2017 and subsequent years, which we have exercised in this proposed rule. Additionally, we have used our discretion to appropriately propose the timing of registration, attestation and payment requirements to allow EPs and eligible organizations as much time as possible in coordination with the anticipated certification of EHR technology to obtain and meaningfully use certified EHRs. We recognize that there may be additional costs that result from various discretionary policy choices by providers. However, those costs cannot be estimated and are not captured in this analysis.

E. Accounting Statement and Table

Whenever a rule is considered a significant rule under Executive Order 12866, we are required to develop an accounting statement indicating the classification of the expenditures associated with the provisions of this proposed rule. Monetary annualized benefits and non-budgetary costs are presented as discounted flows using 3 percent and 7 percent factors in the following Table 15. We are not able to explicitly define the universe of those additional costs, nor specify what the high or low range might be to implement EHR technology in this proposed rule. We note that federal annualized monetized transfers represent the net total of annual incentive payments in the Medicare and Medicaid EHR Incentive programs less

the reductions in Medicare payments to providers failing to demonstrate meaningful use as a result of the related Medicare payment adjustments.

Expected qualitative benefits include improved quality of care, better health outcomes, reduced errors and the like. Private industry costs would include the impact of EHR activities such as temporary reduced staff productivity related to learning how to use the EHR, the need for additional staff to work with HIT issues, and administrative costs related to reporting.

TABLE 15—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES CYS 2017 THROUGH 2020

[In millions]

CATEGORY				
	BENEFITS			
Qualitative	Expected qualitative benefits include improved quality of care, better health outcomes, reduced errors and the like.			
	COSTS			
	Year dollar	Estimates (in millions)	Unit discount rate	Period covered
	.....	Primary Estimate		
Annualized Monetized Costs to Private Industry Associated with Reporting Requirements	2017	$478.1 $478.4	7% 3%	CY 2017
Qualitative—Other private industry costs associated with the adoption of EHR technology.	These costs would include the impact of EHR activities such as reduced staff productivity related to learning how to use the EHR technology, the need for additional staff to work with HIT issues, and administrative costs related to reporting.			
	TRANSFERS			
	Year dollar	Estimates (in millions)	Unit discount rate	Period covered
Federal Annualized Monetized	2017	$1,000.4 $954.8	7% 3%	CYs 2017–2020
From Whom To Whom?	Federal Government to Medicare- and Medicaid-eligible professionals and hospitals.			

F. Conclusion

The previous analysis, together with the remainder of this preamble, provides an RIA. We believe there are many positive effects of adopting EHR on health care providers. We believe there are benefits that can be obtained by eligible hospitals and EPs, including: Reductions in medical recordkeeping costs, reductions in repeat tests, decreases in length of stay, and reduced errors. Health IT can enable providers to deliver health care more efficiently. For example, EHRs can reduce the duplication of diagnostic tests, prompt providers to prescribe cost-effective generic medications, remind patients about preventive care, reduce unnecessary office visits, and assist in managing complex care. We also believe that internal savings will likely come through the reductions in the cost of providing care. We believe that the net effect on individual providers may be positive over time in many cases. Accordingly, we believe that the object of the Regulatory Flexibility Analysis to minimize burden on small entities are met by this proposed rule. We invite public comments on the analysis and request any additional data that would help us determine more accurately the impact on the EPs and eligible hospitals affected by the proposed rule.

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this rule.

List of Subjects in 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 part 495 as set forth below:

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 1. 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).

■ 2. Section 495.4 is amended as follows:

■ A. Adding the definition for ''*Application-program interface (API)*''.

■ B. Revising the definition of ''Certified electronic health record technology''.

■ C. Amending the definition of ''*EHR reporting period*'' by—

■ i. Redesignating paragraphs (1)(i), (1)(ii), (1)(iii) introductory text, (1)(iii)(A), (1)(iii)(B), (1)(iii)(C), (1)(iii)(D), and (1)(iv) as paragraphs (1)(i)(A), (1)(i)(B), (1)(i)(C) introductory text, (1)(i)(C)(*1*), (1)(i)(C)(*2*), (1)(i)(C)(*3*), (1)(1)(C)(*4*), and (1)(i)(D), respectively.

■ ii. Adding new paragraph (1)(i) introductory text.

■ iii. Adding a new paragraph (1)(ii).
■ iv. Redesignating paragraphs (2)(i), (2)(ii), (2)(iii) introductory text, (2)(iii)(A), (2)(iii)(B), (2)(iii)(C), and (2)(iii)(D), as paragraphs (2)(i)(A), (2)(i)(B), (2)(i)(C) introductory text and (2)(i)(C)(*1*), (2)(i)(C)(*2*), (2)(i)(C)(*3*), and (2)(i)(C)(*4*), respectively.
■ v. Adding new paragraph (2)(i) introductory text.
■ vi. Adding a new paragraph (2)(ii).
■ D. Amending the definition of ''*EHR reporting period for a payment adjustment year*'' by:
■ i. Redesignating paragraphs (1)(i)(A), (1)(i)(B), (1)(ii), (1)(iii)(A), and (1)(iii)(B) as paragraphs (1)(i)(A)(*1*), (1)(i)(A)(*2*), (1)(i)(B), (1)(i)(C)(*1*) and (1)(i)(C)(*2*), respectively.
■ ii. In newly redesignated paragraph (1)(i)(A)(*1*), by removing the cross-reference ''paragraphs (1)(i)(B), (ii), and (iii)'' and adding in its place the cross-reference ''paragraphs (1)(i)(A)(*2*), (1)(i)(B), and (1)(i)(C)''.
■ iii. In newly redesignated paragraph (1)(i)(A)(*2*), by removing the cross-reference ''paragraphs (1)(iii) or (iv)'' and adding in its place the cross-reference ''paragraph (1)(i)(C)''.
■ iv. Adding new paragraph (1)(i) introductory text.
■ v. Adding a new paragraph (1)(ii).
■ vi. Redesignating paragraphs (2)(i)(A), (2)(i)(B), (2)(ii), (2)(iii)(A), and (2)(iii)(B) as paragraphs (2)(i)(A)(*1*), (2)(i)(A)(*2*), (2)(i)(B), (2)(i)(C)(*1*) and (2)(i)(C)(*2*), respectively.
■ vii. In newly redesignated paragraph (2)(i)(A)(*1*), by removing the cross-reference ''paragraphs (2)(i)(B), (ii), and (iii)'' and adding in its place the cross-reference ''paragraphs (2)(i)(A)(*2*), (2)(i)(B), and (2)(i)(C)''.
■ viii. In newly redesignated paragraph (2)(i)(A)(*2*), by removing the cross-reference ''paragraph (2)(iii)'' and adding in its place the cross-reference ''paragraph (2)(i)(C)''.
■ ix. Adding new paragraph (2)(i) introductory text.
■ x. Adding new paragraph (2)(ii).
■ xi. Redesignating paragraphs (3)(i) and (3)(ii) as paragraphs (3)(i)(A) and (3)(i)(B).
■ xii. In newly redesignated paragraph (3)(i)(A), by removing the cross-reference ''paragraph (3)(ii)'' and adding in its place the cross-reference ''paragraph (3)(i)(B)''.
■ xiii. Adding new paragraph (3)(i) introductory text.
■ xiv. Adding new paragraph (3)(ii).
■ E. In the paragraph (1) of the definition of ''*Meaningful EHR User*'' by removing the reference ''under § 495.6'' and adding in its place the reference to ''under § 495.6 or 495.7''.

The additions read as follows:

§ 495.4 Definitions.

* * * * *

Application-program interface (API) means a set of programming protocols established for multiple purposes. APIs may be enabled by a provider or provider organization to provide the patient with access to their health information through a third-party application with more flexibility than often found in many current ''patient portals.''

Certified electronic health record technology (CEHRT) means the following:

(1) For any Federal fiscal year (FY) or calendar year (CY) before 2018, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that—

(i) Meets the—

(A) 2014 Edition Base EHR definition (as defined at 45 CFR 170.102); or

(B) 2015 Edition Base EHR definition (as defined at 45 CFR 170.102); or

(ii) Has been certified to the following certification criteria:

(A)(*1*) CPOE at—

(*i*) 45 CFR 170.314(a)(1), (18), (19) or (20); or

(*ii*) 45 CFR 170.315(a)(1), (2) or (3);

(*2*)(*i*) Record demographics at 45 CFR 170.314(a)(3); or

(*ii*) 45 CFR 170.315(a)(5).

(*3*)(*i*) Problem list at 45 CFR 170.314(a)(5); or

(*ii*) 45 CFR 170.315(a)(7).

(*4*)(*i*) Medication list at 45 CFR 170.314(a)(6); or (*ii*) 45 CFR 170.315(a)(8).

(*5*)(*i*) Medication allergy list 45 CFR 170.314(a)(7); or (*ii*) 45 CFR 170.315(a)(9);

(*6*)(*i*) Clinical decision support at 45 CFR 170.314(a)(8); or (*ii*) 45 CFR 170.315(a)(10).

(*7*) Health information exchange at transitions of care at one of the following:

(*i*) 45 CFR 170.314(b)(1) and (2).

(*ii*) 45 CFR 170.314(b)(1), (b)(2), and (h)(1).

(*iii*) 45 CFR 170.314(b)(1), (b)(2), and (b)(8).

(*iv*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), and (h)(1).

(*v*) 45 CFR 170.314(b)(8) and (h)(1).

(*vi*) 45 CFR 170.314(b)(1), (b)(2), and 170.315(h)(2).

(*vii*) 45 CFR 170.314(b)(1), (b)(2), (h)(1), and 170.315(h)(2).

(*viii*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), and 170.315(h)(2).

(*ix*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), and 170.315(h)(2).

(*x*) 45 CFR 170.314(b)(8), (h)(1), and 170.315(h)(2).

(*xi*) 45 CFR 170.314(b)(1), (b)(2), and 170.315(b)(1).

(*xii*) 45 CFR 170.314(b)(1), (b)(2), (h)(1), and 170.315(b)(1).

(*xiii*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), and 170.315(b)(1).

(*xiv*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), and 170.315(b)(1).

(*xv*) 45 CFR 170.314(b)(8), (h)(1), and 170.315(b)(1).

(*xvi*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), 170.315(b)(1), and 170.315(h)(1).

(*xvii*) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), 170.315(b)(1), and 170.315(h)(2).

(*xviii*) 45 CFR 170.314(h)(1) and 170.315(b)(1).

(*xix*) 45 CFR 170.315(b)(1) and (h)(1).

(*xx*) 45 CFR 170.315(b)(1) and (h)(2).

(*xxi*) 45 CFR 170.315(b)(1), (h)(1), and (h)(2).

(B) Clinical quality measures at 45 CFR 170.314(c)(1) or 170.315(c)(1).

(C) The 2014 Edition or 2015 Edition certification criteria that are necessary to be a Meaningful EHR User (as defined in this section), including the following:

(*1*) The applicable automated numerator recording and automated measure calculation certification criteria that support attestation as a Meaningful EHR User at 45 CFR 170.315(g)(1) and (2) and 45 CFR 170.314(g)(1) and (2).

(*2*) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.314(c)(2) and (c)(3) or 45 CFR 170.315(c)(2) and (c)(3).

(2) For 2018 and subsequent years, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102) and has been certified to the 2015 Edition health IT certification criteria that—

(i)(A) Include the capabilities to record 45 CFR 170.315(a)(14); or

(B) Create and incorporate family health history 45 CFR 170.315(a)(15).

(ii) Include the capabilities that support patient health information capture at 45 CFR 170.315(a)(19); and

(iii) Are necessary to be a Meaningful EHR User (as defined in this section), including the following:

(A) The applicable automated numerator recording and automated measure calculation certification criteria that support attestation as a Meaningful EHR User at 45 CFR 170.315(g)(1) and (2).

(B) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures under the 2015 Edition certification criteria 45 CFR 170.315(c)(2) and (c)(3).

* * * * *

EHR reporting period. * * *

(1) * * *

(i) The following are applicable before CY 2017.

* * * * *

(ii) The following are applicable beginning in CY 2017 under the Medicaid EHR Incentive Program:

(A) For the payment year in which the EP is first demonstrating he or she is a meaningful EHR user, any continuous 90-day period within the calendar year.

(B) For the subsequent payment years following the payment year in which the EP first successfully demonstrates he or she is a meaningful EHR user, the calendar year.

(2) * * *

(i) The following are applicable before CY 2017:

* * * * *

(ii) The following are applicable beginning in CY 2017 under the Medicaid EHR Incentive Program:

(A) For the payment year in which the eligible hospital or CAH is first demonstrating it is a meaningful EHR user, any continuous 90-day period within the calendar year.

(B) For the subsequent payment years following the payment year in which the eligible hospital or CAH first successfully demonstrates it is a meaningful EHR user, the calendar year.

EHR reporting period for a payment adjustment year. * * *

(1) * * *

(i) The following are applicable before CY 2017:

* * * * *

(ii) The following are applicable beginning in CY 2017:

(A) Except as provided under paragraph (1)(ii)(B) of this definition, the calendar year that is 2 years before the payment adjustment year.

(B) If an EP is demonstrating under the Medicaid EHR Incentive Program that he or she is a meaningful EHR user for the first time in the calendar year that is 2 years before the payment adjustment year, then the continuous 90-day period that is the EHR reporting period for the Medicaid incentive payment within such (2 years prior) calendar year.

(2) * * *

(i) The following are applicable before CY 2017:

* * * * *

(ii) The following are applicable beginning in CY 2017:

(A) Except as provided in paragraph (2)(ii)(B) of this definition, the calendar year that is 2 years before the payment adjustment year.

(B) If an eligible hospital is demonstrating under the Medicaid EHR Incentive Program that it is a meaningful EHR user for the first time in the calendar year that is 2 years before the payment adjustment year, then the continuous 90-day period that is the EHR reporting period for the Medicaid incentive payment within such (2 years prior) calendar year.

(3) * * *

(i) The following are applicable before CY 2017:

* * * * *

(ii) The following are applicable beginning in CY 2017:

(A) Except as provided in paragraph (3)(ii)(B) of this definition, the calendar year that begins on the first day of the second quarter of the Federal fiscal year that is the payment adjustment year.

(B) If a CAH is demonstrating under the Medicaid EHR Incentive Program that it is a meaningful EHR user for the first time in the calendar year that begins on the first day of the second quarter of the Federal fiscal year that is the payment adjustment year, then any continuous 90-day period within such calendar year.

* * * * *

■ 3. Section 495.6 is amended by revising the section heading and adding introductory text to read as follows:

§ 495.6 Meaningful use objectives and measures for EPs, eligible hospitals, and CAHs before 2018.

The following criteria are applicable before 2018:

* * * * *

■ 4. Section 495.7 is added to read as follows:

§ 495.7 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals, and CAHs for 2018 and subsequent years.

The following criteria are optional for EPs, eligible hospitals, and CAHs in 2017 as outlined at § 495.8(a)(2)(i)(E)(*3*) and (b)(2)(E)(*3*) and applicable for all EPs, eligible hospitals, and CAHs for 2018 and subsequent years:

(a) *Stage 3 criteria for EPs.*

(1) *General rule regarding Stage 3 criteria for meaningful use for EPs.* Except as specified in paragraphs (a)(2) through (a)(3) of this section, EPs must meet all objectives and associated measures of the Stage 3 criteria specified in paragraph (d) of this section to meet the definition of a meaningful EHR user.

(2) *Selection of measures for specified objectives in paragraph (d) of this section.* An EP may meet the criteria for 2 out of the 3 measures associated with an objective, rather than meeting the criteria for all 3 of the measures, if the EP meets all of the following requirements:

(i) Must ensure that the objective in paragraph (d) of this section includes an option to meet 2 out of the 3 associated measures.

(ii) Meets the threshold for 2 out of the 3 measures for that objective.

(iii) Attests to all 3 of the measures for that objective

(3) *Exclusion for nonapplicable objectives and measures.*

(i) An EP may exclude a particular objective that includes an option for exclusion contained in paragraph (d) of this section, if the EP meets all of the following requirements:

(A) Meets the criteria in the applicable objective that would permit the exclusion.

(B) Attests to the exclusion.

(ii) An EP may exclude a measure within an objective which allows for a provider to meet the threshold for 2 of the 3 measures, as outlined in paragraph (a)(2) of this section, in the following manner:

(A)(*1*) Meets the criteria in the applicable measure or measures that would permit the exlusion; and

(*2*) Attests to the exclusion or exclusions.

(B)(*1*) Meets the threshold; and

(*2*) Attests to any remaining measure or measures.

(4) *Exception for Medicaid EPs who adopt, implement or upgrade in their first payment year.* For Medicaid EPs who adopt, implement or upgrade its certified EHR technology in their first payment year, the meaningful use objectives and associated measures of the Stage 3 criteria specified in paragraph (d) of this section, apply beginning with the second payment year, and do not apply to the first payment year.

(b) *Stage 3 criteria for eligible hospitals and CAHs.*

(1) *General rule regarding Stage 3 criteria for meaningful use for eligible hospitals or CAHs.* Except as specified in paragraphs (b)(2) through (b)(3) of this section, eligible hospitals and CAHs must meet all objectives and associated measures of the Stage 3 criteria specified in paragraph (d) of this section to meet the definition of a meaningful EHR user.

(2) *Selection of measures for specified objectives in paragraph (d) of this section.* An eligible hospital or CAH may meet the criteria for 2 out of the 3 measures associated with an objective, rather than meeting the criteria for all 3 of the measures, if the eligible hospital or CAH meets all of the following requirements:

(i) Must ensure that the objective in paragraph (d) of this section includes an option to meet 2 out of the 3 associated measures.

(ii) Meets the threshold for 2 out of the 3 measures for that objective.

(iii) Attests to all 3 of the measures for that objective.

(3) *Exclusion for nonapplicable objectives and measures.*

(i) An eligible hospital or CAH may exclude a particular objective that includes an option for exclusion contained in paragraph (d) of this section, if the eligible hospital or CAH meets all of the following requirements:

(A) Meets the criteria in the applicable objective that would permit the exclusion.

(B) Attests to the exclusion.

(ii) An eligible hospital or CAH may exclude a measure within an objective which allows for a provider to meet the threshold for 2 of the 3 measures, as outlined in paragraph (b)(2) of this section, in the following manner:

(A)(*1*) Meets the criteria in the applicable measure or measures that would permit the exclusion; and

(2) Attests to the exclusion or exclusions.

(B)(*1*) Meets the threshold; and

(*2*) Attests to any remaining measure or measures.

(4) *Exception for Medicaid eligible hospitals or CAHs that adopt, implement or upgrade in their first payment year.* For Medicaid eligible hospitals or CAHs who adopt, implement or upgrade certified EHR technology in their first payment year, the meaningful use objectives and associated measures of the Stage 3 criteria specified in paragraph (d) of this section apply beginning with the second payment year, and do not apply to the first payment year.

(c) *Objectives and associated measures in paragraph (d) of this section that rely on measures that count unique patients or actions.*

(1) If a measure (or associated objective) in paragraph (d) of this section references paragraph (c) of this section, then the measure may be calculated by reviewing only the actions for patients whose records are maintained using certified EHR technology. A patient's record is maintained using certified EHR technology if sufficient data was entered in the certified EHR technology to allow the record to be saved, and not rejected due to incomplete data.

(2) If the objective and associated measure does not reference this paragraph (c) of this section, then the measure must be calculated by reviewing all patient records, not just those maintained using certified EHR technology.

(d) *Stage 3 objectives and measures for EPs, eligible hospitals, and CAHs.*

(1) *Protect patient health information.*

(i) *EP protect patient health information.*

(A) *Objective.* Protect electronic protected health information (ePHI) created or maintained by the certified EHR technology (CEHRT) through the implementation of appropriate technical, administrative, and physical safeguards.

(B) *Measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including:

(*1*) Addressing the security (including encryption) of data stored in CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3),

(*2*) Implement security updates as necessary, and

(*3*) Correct identified security deficiencies as part of the EP's risk management process.

(ii) *Eligible hospital/CAH protect patient health information.*

(A) *Objective.* Protect electronic protected health information (ePHI) created or maintained by the certified EHR technology (CEHRT) through the implementation of appropriate technical, administrative, and physical safeguards.

(B) *Measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including—

(*1*) Addressing the security (including encryption) of data stored in CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3);

(*2*) Implement security updates as necessary; and

(3) Correct identified security deficiencies as part of the eligible hospital's or CAH's risk management process.

(2) *Electronic prescribing.*

(i) EP *electronic prescribing.*

(A) *Objective.* Generate and transmit permissible prescriptions electronically (eRx).

(B) *Measure.* Subject to paragraph (c) of this section, more than 80 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using certified EHR technology (CEHRT).

(C) *Exclusions in accordance with paragraph (a)(3) of this section.*

(*1*) Any EP who writes fewer than 100 permissible prescriptions during the EHR reporting period; or

(*2*) Any EP who does not have a pharmacy within its organization and there are no pharmacies that accept electronic prescriptions within 10 miles of the EP's practice location at the start of his/her EHR reporting period.

(ii) *Eligible hospital/CAH electronic prescribing.*

(A) *Objective.* Generate and transmit permissible discharge prescriptions electronically (eRx).

(B) *Measure.* Subject to paragraph (c) of this section, more than 25 percent of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using certified EHR technology (CEHRT).

(C) *Exclusions in accordance with paragraph (b)(3) of this section.* Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of the eligible hospital's or CAH's EHR reporting period.

(3) *Clinical decision support.*

(i) *EP clinical decision support.*

(A) *Objective.* Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

(B) *Measures.*

(*1*) Implement five clinical decision support interventions related to four or more clinical quality measures (CQMs) at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an EP's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions; and

(*2*) The EP has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

(C) *Exclusion in accordance with paragraph (a)(3) of this section for paragraph (d)(3)(i)(B)(2) of this section.* An EP who writes fewer than 100 medication orders during the EHR reporting period.

(ii) *Eligible hospital/CAH clinical decision support.*

(A) *Objective.* Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

(B) *Measures.*

(*1*) Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures (CQMs) related to an eligible hospital or CAH's patient population, the clinical decision support interventions must be related to high-priority health conditions; and

(*2*) The eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug-

allergy interaction checks for the entire EHR reporting period.

(4) *Computerized provider order entry (CPOE).*

(i) *EP CPOE.*

(A) *Objective.* Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.

(B) *Measures.* Subject to paragraph (c) of this section—

(*1*) More than 80 percent of medication orders created by the EP during the EHR reporting period are recorded using computerized provider order entry;

(*2*) More than 60 percent of laboratory orders created by the EP during the EHR reporting period are recorded using computerized provider order entry; and

(*3*) More than 60 percent of diagnostic imaging orders created by the EP during the EHR reporting period are recorded using computerized provider order entry.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.*

(*1*) For the measure specified in paragraph (d)(4)(i)(B)(*1*) of this section, any EP who writes fewer than 100 medication orders during the EHR reporting period.

(*2*) For the measure specified in paragraph (d)(4)(i)(B)(*2*) of this section, any EP who writes fewer than 100 laboratory orders during the EHR reporting period.

(*3*) For the measure specified in paragraph (d)(4)(i)(B)(*3*) of this section, any EP who writes fewer than 100 diagnostic imaging orders during the EHR reporting period.

(ii) *Eligible hospital and CAH CPOE.*

(A) *Objective.* Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.

(B) *Measures.* Subject to paragraph (c) of this section, more than—

(*1*) Eighty percent of medication orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry;

(*2*) Sixty percent of laboratory orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry; and

(*3*) Sixty percent of diagnostic imaging orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

(5) *Patient electronic access to health information.*

(i) *EP patient electronic access to health information.*

(A) *Objective.* The EP provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an application-program interface (API), within 24 hours of its availability.

(B) *Measures. EPs must meet the following two measures:*

(*1*) For more than 80 percent of all unique patients seen by the EP)—

(*i*) The patient (or patient authorized representatives) is provided access to view online, download, and transmit their health information within 24 hours of its availability to the provider; or

(*ii*) The patient (or patient authorized representatives) is provided access to an ONC-certified application-program interface (API) that can be used by third-party applications or devices to provide patients (or patient authorized representatives) access to their health information, within 24 hours of its availability to the provider.

(*2*) The EP must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients seen by the EP during the EHR reporting period.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.*

(*1*) Any EP who has no office visits during the reporting period may exclude from the measures specified in paragraphs (d)(7)(i)(B)(*1*) and (B)(*2*) of this section.

(*2*) Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(7)(i)(B)(*1*) and (*2*) of this section.

(ii) *Eligible hospital and CAH patient electronic access to health information.*

(A) *Objective.* The eligible hospital or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an application-program interface (API), within 24 hours of its availability.

(B) *Measures.* Eligible hospitals and CAHs must meet the following two measures:

(*1*) For more than 80 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23)—

(*i*) The patient (or patient authorized representatives) is provided access to view online, download, and transmit their health information within 24 hours of its availability to the provider; or

(*ii*) The patient (or patient authorized representatives) is provided access to an ONC-certified application-program interface (API) that can be used by third-party applications or devices to provide patients (or patient authorized representatives) access to their health information, within 24 hours of its availability to the provider.

(*2*) The eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

(C) *Exclusion in accordance with paragraph (b)(3) of this section.* Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period is excluded from the measures specified in paragraphs (d)(7)(ii)(B)(*1*) and (*2*) of this section.

(6) *Coordination of care through patient engagement.*

(i) *EP coordination of care through patient engagement.*

(A) *Objective.* Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.

(B) *Measures.* In accordance with paragraph (a)(2) of this section, an EP must satisfy 2 out of the 3 following measures in paragraphs (d)(5)(i)(B)(*1*), (*2*), and (*3*) of this section except those measures for which an EP qualifies for

an exclusion under paragraph (a)(3) of this section.

(*1*) During the EHR reporting period, more than 25 percent of all unique patients seen by the EP actively engage with the electronic health record made accessible by the provider. An EP may meet measure specified in paragraph (d)(5)(i)(B)(*1*) of this paragraph by either—

(*i*) More than 25 percent of all unique patients (or patient-authorized representatives) seen by the EP during the EHR reporting period view, download or transmit to a third party their health information; or

(*ii*) More than 25 percent of all unique patients (or patient-authorized representatives) seen by the EP during the EHR reporting period access their health information through the use of an ONC-certified API that can be used by third-party applications or devices.

(*2*) For more than 35 percent of all unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient.

(*3*) Patient generated health data or data from a nonclinical setting is incorporated into the certified EHR technology for more than 15 percent of all unique patients seen by the EP during the EHR reporting period.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.*

(*1*) Any EP who has no office visits during the reporting period may exclude from the measures specified in paragraphs (d)(5)(i)(B)(*1*), (B)(*2*) and (B)(*3*) of this section.

(*2*) Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(5)(i)(B)(*1*), (B)(*2*) and (B)(*3*) of this section.

(ii) *Eligible hospital and CAH coordination of care through patient engagement.*

(A) *Objective.* Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.

(B) *Measures.* In accordance with paragraph (b)(2) of this section, an eligible hospital or CAH must satisfy 2 of the 3 following measures in paragraph (d)(5)(ii)(B)(*1*), (*2*), and (*3*) of this section, except those measures for which an eligible hospital or CAH qualifies for an exclusion under paragraph (b)(3) of this section.

(*1*) During the EHR reporting period, more than 25 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the electronic health record made accessible by the provider. An eligible hospital or CAH may meet the measure specified in paragraph (d)(5)(ii)(B)(*1*) of this section by having—

(*i*) More than 25 percent of all unique patients (or patient-authorized representatives) discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period view, download or transmit to a third party their health information; or

(*ii*) More than 25 percent of all unique patients (or patient-authorized representatives) discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period access their health information through the use of an ONC-certified API that can be used by third-party applications or devices.

(*2*) For more than 35 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient.

(*3*) Patient generated health data or data from a non-clinical setting is incorporated into the certified EHR technology for more than 15 percent of unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

(C) *Exclusions under paragraph (b)(3) of this section.*

(*1*) Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in pargraphs (d)(5)(ii)(B)(*1*), (B)(*2*), and (B)(*3*) of this section.

(7) *Health information exchange.*

(i) *EP health information exchange.*

(A) *Objective.* The EP provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of certified EHR technology.

(B) *Measures.* In accordance with paragraph (a)(2) of this section, an EP must attest to all 3 measures, but must meet the threshold for 2 of the 3 measures in paragraph (d)(6)(i)(B)(*1*), (*2*), and (*3*), in order to meet the objective. Subject to paragraph (c) of this section—

(*1*) *Measure 1.* For more than 50 percent of transitions of care and referrals, the EP that transitions or refers their patient to another setting of care or provider of care—

(*i*) Creates a summary of care record using CEHRT; and

(*ii*) Electronically exchanges the summary of care record.

(*2*) *Measure 2.* For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP incorporates into the patient's EHR an electronic summary of care document from a source other than the provider's EHR system.

(*3*) *Measure 3.* For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP performs clinical information reconciliation. The EP must implement clinical information reconciliation for the following three clinical information sets:

(*i*) *Medication.* Review of the patient's medication, including the name, dosage, frequency, and route of each medication.

(*ii*) *Medication allergy.* Review of the patient's known allergic medications.

(*iii*) *Current problem list.* Review of the patient's current and active diagnoses.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.* An EP must be excluded when any of the following occur:

(*1*) An EP neither transfers a patient to another setting nor refers a patient to another provider during the EHR reporting period must be excluded from paragraph (d)(6)(i)(B)(*1*) of this section.

(*2*) Any EP for whom the total of transitions or referrals recieved and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period may be excluded from paragraphs (d)(6)(i)(B)(*2*) and (d)(6)(i)(B)(*3*) of this section.

(*3*) Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units

with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(6)(i)(B)(*1*), (B)(*2*) and (B)(*3*) of this section.

(ii) *Eligible hospitals and CAHs health information exchange.*

(A) *Objective.* The eligible hospital or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a their new patient, and incorporates summary of care information from other providers into EHR using the functions of certified EHR technology.

(B) *Measures.* In accordance with paragraph (b)(2) of this section, an eligible hospital or CAH must attest to all three measures, but must meet the threshold for 2 of the 3 measures in paragraph (d)(6)(ii)(B)(*1*), (*2*), and (*3*). Subject to paragraph (c) of this section—

(*1*) *Measure 1.* For more than 50 percent of transitions of care and referrals, the eligible hospital or CAH that transitions or refers its patient to another setting of care or provider of care—

(*i*) Creates a summary of care record using CEHRT; and

(*ii*) Electronically exchanges the summary of care record.

(*2*) *Measure 2.* For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH incorporates into the patient's EHR an electronic summary of care document from a source other than the provider's EHR system.

(*3*) *Measure 3.* For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH performs a clinical information reconciliation. The provider must implement clinical information reconciliation for the following three clinical information sets:

(*i*) *Medication.* Review of the patient's medication, including the name, dosage, frequency, and route of each medication.

(*ii*) *Medication allergy.* Review of the patient's known allergic medications.

(*iii*) *Current problem list.* Review of the patient's current and active diagnoses.

(C) *Exclusions in accordance with paragraph (b)(3) of this section.*

(*1*) Any eligible hospital or CAH for whom the total of transitions or referrals recieved and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period may be excluded from paragraphs (d)(6)(i)(B)(*2*) and (d)(6)(i)(B)(*3*) of this section.

(*2*) Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(6)(ii)(B)(*1*), (*2*) and (*3*) of this section.

(8) *Public Health and Clinical Data Registry Reporting.*

(i) *EP Public Health and Clinical Data Registry: Reporting objective.*

(A) *Objective.* The EP is in active engagement with a public health agency (PHA) or clinical data registry (CDR) to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

(B) *Measures.* In order to meet the objective under paragraph (d)(8)(i)(A) of this section, an EP must choose from measures 1 through 5 (paragraphs (d)(8)(i)(B)(*1*) through (d)(8)(i)(B)(*5*) of this section) and must successfully attest to any combination of three measures. These measures may be met by any combination, including meeting measure specified in paragraph (d)(8)(i)(B)(*4*) or (*5*) of this section multiple times, in accordance with applicable law and practice:

(*1*) *Immunization registry reporting:* The EP is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

(*2*) *Syndromic surveillance reporting.* The EP is in active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care ambulatory setting.

(*3*) *Case reporting.* The EP is in active engagement with a public health agency to submit case reporting of reportable conditions.

(*4*) *Public health registry reporting.* The EP is in active engagement with a public health agency to submit data to public health registries.

(*5*) *Clinical data registry reporting.* The EP is in active engagement to submit data to a clinical data registry.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.*

(*1*) Any EP meeting one or more of the following criteria may be excluded from the immunization registry reporting measure in paragraph (d)(8)(i)(B)(*1*) of this section if the EP:

(*i*) Does not administer any immunizations to any of the populations for which data is collected by their jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(*ii*) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of its EHR reporting period.

(*iii*) Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data at the start of the EHR reporting period.

(*2*) Any EP meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure described in paragraph (d)(8)(i)(B)(*2*) of the section if the EP:

(*i*) Does not treat or diagnose or directly treat any disease or condition associated with a syndromic surveillance system in the EP's jurisdiction.

(*ii*) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data at the start of the EHR reporting period.

(*3*) Any EP meeting one or more of the following criteria may be excluded from the case reporting measure at paragraph (d)(8)(i)(B)(*3*) of this section if the EP:

(*i*) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period.

(*ii*) Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data at the start of the EHR reporting period.

(*4*) Any EP meeting at least one of the following criteria may be excluded from the public health registry reporting measure specified in paragraph (d)(8)(i)(B)(*4*) of this section if the EP:

(*i*) Does not diagnose or directly treat any disease or condition associated with a public health registry in the EP's jurisdiction during the EHR reporting period.

(*ii*) Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no public health registry for which the EP is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

(*5*) Any EP meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure specified in paragraph (d)(8)(i)(B)(*5*) of this section if the EP:

(*i*) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period;

(*ii*) Operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no clinical data registry for which the EP is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

(ii) *Eligible hospital and CAH Public Health and Clinical Data Registry: Reporting objective.*

(A) *Objective.* The eligible hospital or CAH is in active engagement with a public health agency (PHA) or clinical data registry (CDR) to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

(B) *Measures.* In order to meet the objective under paragraph (d)(8)(ii)(A) of this section, an eligible hospital or CAH must choose from measures 1 through 6 (as described in paragraphs (d)(8)(ii)(B)(*1*) through (d)(8)(ii)(B)(*6*) of this section) and must successfully attest to any combination of four measures. These measures may be met by any combination, including meeting the measure specified in paragraph (d)(8)(ii)(B)(*4*) or (*5*) of this section multiple times, in accordance with applicable law and practice:

(*1*) *Immunization registry reporting.* The eligible hospital or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

(*2*) *Syndromic surveillance reporting.* The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an emergency or urgent care department (POS 23).

(*3*) *Case reporting.* The eligible hospital or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.

(*4*) *Public health registry reporting.* The eligible hospital or CAH is in active engagement with a public health agency to submit data to public health registries.

(*5*) *Clinical data registry reporting.* The eligible hospital or CAH is in active engagement to submit data to a clinical data registry.

(*6*) *Electronic reportable laboratory result reporting.* The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results.

(C) *Exclusions in accordance with paragraph (b)(3) of this section.*

(*1*) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from to the immunization registry reporting measure specified in paragraph (d)(8)(ii)(B)(*1*) of this section if the eligible hospital or CAH:

(*i*) Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(*ii*) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data at the start of the EHR reporting period.

(*2*) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure specified in paragraph (d)(8)(ii)(B)(*2*) of this section if the eligible hospital or CAH:

(*i*) Does not have an emergency or urgent care department.

(*ii*) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data at the start of the EHR reporting period.

(*3*) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure specified in paragraph (d)(8)(ii)(B)(*3*) of this section if the eligible hospital or CAH:

(*i*) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period.

(*ii*) Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of their EHR reporting period.

(*iii*) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data at the start of the EHR reporting period.

(*4*) Any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure specified in paragraph (d)(8)(ii)(B)(*4*) of this section if the eligible hospital or CAH:

(*i*) Does not diagnose or directly treat any disease or condition associated with a public health registry in its jurisdiction during the EHR reporting period.

(*ii*) Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no public health registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

(*5*) Any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure specified in paragraph (d)(8)(ii)(B)(*5*) of this section if the eligible hospital or CAH:

(*i*) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period.

(*ii*) Operates in a jurisdiction for which no clinical data registry is

capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no clinical data registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

(*6*) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result reporting measure specified in paragraph (d)(8)(ii)(B)(*6*) of this section if the eligible hospital or CAH:

(*i*) Does not perform or order laboratory tests that are reportable in its jurisdiction during the EHR reporting period.

(*ii*) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results at the start of the EHR reporting period.

■ 5. Section 495.8 is amended as follows:

■ A. In paragraph (a) introductory text, by removing the cross-reference ''under § 495.6 of this subpart'' and adding in its place the cross-reference ''under § 495.6 or § 495.7''.

■ B. In paragraph (a)(1)(i)(B), by removing the cross-reference ''under § 495.6(d) and § 495.6(e) of this subpart'' and adding in its place the cross-reference ''under § 495.6 or § 495.7''.

■ C. In paragraph (a)(1)(iii), by removing the cross-reference ''in § 495.6 and § 495.8 of this subpart'' and adding in its place the cross-reference ''in § 495.6 or § 495.7 and § 495.8''.

■ D. In paragraph (a)(2)(i)(B), by removing the cross-reference ''under § 495.6'' and adding in its place the cross-reference ''under § 495.6 or § 495.7''.

■ E. Adding paragraph (a)(2)(i)(E).

■ F. In paragraph (a)(2)(iv), by removing the cross-reference ''in § 495.6 and § 495.8 of this subpart'' and adding in its place the cross-reference ''in § 495.6 or § 495.7 and § 495.8''.

■ G. In paragraph (b)(1)(i)(B), by removing the cross-reference ''under § 495.6(f) and § 495.6(g)'' and adding in its place the cross-reference ''under § 495.6 or § 495.7''.

■ H. Redesignating paragraph (b)(1)(iv) and paragraph (b)(1)(iii).

■ I. In newly redesignated paragraph (b)(1)(iii), by removing the cross-reference ''in § 495.6 and § 495.8 of this subpart'' and adding in its place the cross-reference ''in § 495.6 or § 495.7 and § 495.8''.

■ J. In paragraph (b)(2)(i)(B), by removing the cross-reference ''under § 495.6'' and adding in its place the cross-reference ''under § 495.6 or § 495.7''.

■ K. Adding paragraph (b)(2)(i)(E).

The additions read as follows:

§ 495.8 Demonstration of meaningful use criteria.

(a) * * *

(2) * * *

(i) * * *

(E) For 2017 only, an EP may attest to the following:

(*1*) Stage 1 objectives and measures outlined at § 495.6 if the EP has never before demonstrated meaningful use, or if the EP previously demonstrated meaningful use for the first time in 2015 or 2016.

(*2*) Stage 2 objectives and measures outlined at § 495.6 if the EP previously demonstrated meaningful use for any year prior to 2017.

(*3*) Stage 3 objectives and measures outlined at § 495.7 if the EP has never before demonstrated meaningful use or if the EP has demonstrated meaningful use for any year prior to 2017.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(E) For 2017 only, an eligible hospital or CAH may attest to the following:

(*1*) Stage 1 objectives and measures outlined at § 495.6 if the eligible hospital or CAH has never before demonstrated meaningful use, or if the eligible hospital or CAH previously demonstrated meaningful use for the first time in 2015 or 2016.

(*2*) Stage 2 objectives and measures outlined at § 495.6 if the eligible hospital or CAH previously demonstrated meaningful use for any year prior to 2017.

(*3*) Stage 3 objectives and measures outlined at § 495.7 if the eligible hospital or CAH has never before demonstrated meaningful use or if the eligible hospital or CAH has demonstrated meaningful use for any year prior to 2017.

* * * * *

■ 6. Section 495.316 is amended by revising paragraph (c) introductory text and adding paragraphs (d)(2)(iii), (f), (g), and (h) to read as follows:

§ 495.316 State monitoring and reporting regarding activities required to receive an incentive payment.

* * * * *

(c) Subject to § 495.332 and § 495.352, the State is required to submit to CMS annual reports, in the manner prescribed by CMS, on the following:

* * * * *

(d) * * *

(2) * * *

(iii) Subject to § 495.332, the State may propose a revised definition for Stage 3 of meaningful use of certified EHR technology, subject to CMS prior approval, but only with respect to the public health and clinical data registry reporting objective described in § 495.7(d)(8).

* * * * *

(f) Each State must submit to CMS the annual report described in paragraph (c) of this section within 45 days of the end of the second quarter of the Federal fiscal year.

(g) The State must, on a quarterly basis and in the manner prescribed by CMS, submit a report(s) on the following:

(1) The State and payment year to which the quarterly report pertains.

(2) Subject to paragraph (h)(2) of this section, provider-level attestation data for each EP and eligible hospital that attests to demonstrating meaningful use for each payment year beginning with 2013.

(h)(1) Subject to paragraph (h)(2) of this section, the quarterly report described in paragraph (g) of this section must include the following for each EP and eligible hospital:

(i) The payment year number.

(ii) The provider's National Provider Identifier or CCN, as appropriate.

(iii) Attestation submission date.

(iv) The state qualification.

(v) The state qualification date, which is the beginning date of the provider's EHR reporting period for which it demonstrated meaningful use.

(vi) The State disqualification, if applicable.

(vii) The State disqualification date, which is the beginning date of the provider's EHR reporting period to which the provider attested but for which it did not demonstrate meaningful use, if applicable.

(2) The quarterly report described in paragraph (g) of this section is not required to include information on EPs who are eligible for the Medicaid EHR incentive program on the basis of being a nurse practitioner, certified nurse-midwife or physician assistant.

■ 7. Section 495.352 is revised to read as follows:

§ 495.352 Reporting requirements.

(a) Each State must submit to HHS on a quarterly basis a progress report, in the

manner prescribed by HHS, documenting specific implementation and oversight activities performed during the quarter, including progress in implementing the State's approved Medicaid HIT plan.

(b) The quarterly progress reports must include, but need not be limited to providing, updates on the following:

(1) State system implementation dates.

(2) Provider outreach.

(3) Auditing.

(4) State-specific State Medicaid HIT Plan tasks.

(5) State staffing levels and changes.

(6) The number and type of providers that qualified for an incentive payment on the basis of having adopted, implemented or upgraded certified EHR technology and the amounts of incentive payments.

(7) The number and type of providers that qualified for an incentive payment on the basis of having demonstrated that they are meaningful users of certified EHR technology and the amounts of incentive payments.

Dated: March 10, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: March 18, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015–06685 Filed 3–20–15; 3:00 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 170

RIN 0991–AB93

2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking with comment period.

SUMMARY: This notice of proposed rulemaking introduces a new edition of certification criteria (the 2015 Edition health IT certification criteria or ''2015 Edition''), proposes a new 2015 Edition Base EHR definition, and proposes to modify the ONC Health IT Certification Program to make it open and accessible to more types of health IT and health IT that supports various care and practice settings. The 2015 Edition would also establish the capabilities and specify the related standards and implementation specifications that Certified Electronic Health Record (EHR) Technology (CEHRT) would need to include to, at a minimum, support the achievement of meaningful use by eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) under the Medicare and Medicaid EHR Incentive Programs (EHR Incentive Programs) when such edition is required for use under these programs.

DATES: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, no later than 5 p.m. on May 29, 2015.

ADDRESSES: You may submit comments, identified by RIN 0991–AB93, by any of the following methods (please do not submit duplicate comments). Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

- *Federal eRulemaking Portal:* Follow the instructions for submitting comments. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word. *http://www.regulations.gov.*
- *Regular, Express, or Overnight Mail:* Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention: 2015 Edition Health IT Certification Criteria Proposed Rule, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave SW., Washington, DC 20201. Please submit one original and two copies.
- *Hand Delivery or Courier:* Office of the National Coordinator for Health Information Technology, Attention: 2015 Edition Health IT Certification Criteria Proposed Rule, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave SW., Washington, DC 20201. Please submit one original and two copies. (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 mail drop slots located in the main lobby of the building.)

Enhancing the Public Comment Experience: To facilitate public comment on this proposed rule, a copy will be made available in Microsoft Word format. We believe this version will make it easier for commenters to access and copy portions of the proposed rule for use in their individual comments. Additionally, a separate document will be made available for the public to use to provide comments on the proposed rule. This document is meant to provide the public with a simple and organized way to submit comments on the certification criteria, associated standards and implementation specifications, and respond to specific questions posed in the preamble of the proposed rule. While use of this document is entirely voluntary, we encourage commenters to consider using the document in lieu of unstructured comments or to use it as an addendum to narrative cover pages. Roughly 30% of the public comments submitted to our past two editions of certification criteria proposed rules used the provided template, which greatly assisted in our ability to rapidly process and more accurately categorize public comments. Because of the technical nature of this proposed rule, we believe that use of the document may facilitate our review and understanding of the comments received. The Microsoft Word version of the proposed rule and the document that can be used for providing comments can be found at *http://www.regulations.gov* as part of this proposed rule's docket and on ONC's Web site (*http://www.healthit.gov*).

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. Such information includes, but is not limited to: a person's social security number; date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered proprietary. We will post all comments that are received before the close of the comment period at *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or the Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave SW., Washington,

DC 20201 (call ahead to the contact listed below to arrange for inspection).

FOR FURTHER INFORMATION CONTACT: Michael Lipinski, Office of Policy, Office of the National Coordinator for Health Information Technology, 202–690–7151.

SUPPLEMENTARY INFORMATION:

Commonly Used Acronyms

API Application Programming Interface
CAH Critical Access Hospital
CDA Clinical Document Architecture
CDC Centers for Disease Control and Prevention
CDS Clinical Decision Support
CEHRT Certified Electronic Health Record Technology
CFR Code of Federal Regulations
CHPL Certified Health IT Product List
CLIA Clinical Laboratory Improvement Amendments
CMS Centers for Medicare & Medicaid Services
CQM Clinical Quality Measure
EHR Electronic Health Record
HHS Department of Health and Human Services
HISP Health Information Service Providers
HIT Health Information Technology
HITPC HIT Policy Committee
HITSC HIT Standards Committee
HL7 Health Level Seven
IG Implementation Guide
LOINC® Logical Observation Identifiers Names and Codes
ONC Office of the National Coordinator for Health Information Technology
SNOMED CT® Systematized Nomenclature of Medicine Clinical Terms

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I. Executive Summary

A. Purpose of Regulatory Action

Building on past rulemakings, this proposed rule further identifies how health IT certification can support the establishment of an interoperable nationwide health information infrastructure. It reflects stakeholder feedback received through various outreach initiatives, including the regulatory process, and is designed to broadly support the health care continuum through the use of certified health IT. To achieve this goal, this rule proposes to:

- Improve interoperability for specific purposes by adopting new and updated vocabulary and content standards for the structured recording and exchange of health information, including a Common Clinical Data Set composed primarily of data expressed using adopted standards; and rigorously testing an identified content exchange standard (Consolidated Clinical Document Architecture (C–CDA));
- Facilitate the accessibility and exchange of data by including enhanced data portability, transitions of care, and application programming interface (API) capabilities in the 2015 Edition Base EHR definition;
- Establish a framework that makes the ONC Health IT Certification Program open and accessible to more types of health IT, health IT that supports a variety of care and practice settings, various HHS programs, and public and private interests;
- Support the Medicare and Medicaid EHR Incentive Programs (EHR Incentive Programs) through the adoption of a set of certification criteria that align with proposals for Stage 3;
- Address health disparities by providing certification: To standards for the collection of social, psychological, and behavioral data; for the exchange of sensitive health information (Data Segmentation for Privacy); and for the accessibility of health IT;
- Ensure all health IT presented for certification possess the relevant privacy and security capabilities;
- Improve patient safety by: Applying enhanced user-center design principles to health IT, enhancing patient matching, requiring relevant patient information to be exchanged (*e.g.,* Unique Device Identifiers), improving the surveillance of certified health IT, and making more information about certified products publicly available and accessible;
- Increase the reliability and transparency of certified health IT through surveillance and disclosure requirements; and
- Provide health IT developers with more flexibility and *opportunities* for certification that support both interoperability and innovation.

B. Summary of Major Provisions

1. Overview of the 2015 Edition Health IT Certification Criteria

The 2015 Edition health IT certification criteria (''2015 Edition'') would facilitate greater interoperability for several clinical health information purposes and enable health information exchange through new and enhanced certification criteria, standards, and implementation specifications. It incorporates changes that are designed to spur innovation, open new market opportunities, and provide more choices to providers when it comes to electronic

health information exchange. To achieve these goals, we propose a new ''Application Access to Common Clinical Data Set'' certification criterion that would require the demonstration of an API that responds to data requests for any one of the data referenced in the Common Clinical Data Set as well as for all of the data referenced in the Common Clinical Data Set. To further validate the continued interoperability of certified health IT and the ability to exchange health information, we propose a new certification criterion that would rigorously assess a product's C–CDA creation performance (for both C–CDA version 1.1 and 2.0) when presented for certification for such capabilities.

2. Definitions

a. Base EHR Definitions

We propose to adopt a Base EHR definition specific to the 2015 Edition (*i.e.,* a 2015 Edition Base EHR definition) at § 170.102 and rename the current Base EHR definition at § 170.102 as the 2014 Edition Base EHR definition. For the proposed 2015 Edition Base EHR definition, it would differ from the 2014 Edition Base EHR definition in the following ways:

- It does not include privacy and security capabilities and certification criteria. We believe privacy and security capabilities would be more appropriately addressed through our new proposed approach for the privacy and security certification of Health IT Modules to the 2015 Edition, as discussed under ''Privacy and Security'' in section IV.C.1 of the preamble. Our new privacy and security approach would eliminate eligible professionals (EPs)', eligible hospitals', and critical access hospitals (CAHs)' responsibilities to ensure that they have technology certified to all the necessary privacy and security criteria. Rather, as part of certification, health IT developers would need to meet applicable privacy and security certification criteria.
- It only includes the capability to record and export CQM data (§ 170.315(c)(1)). To note, the capabilities to import, calculate and report CQM data are not included in the proposed 2015 Edition Base EHR definition or any other CQM-related requirements. Please refer to the ''Clinical Quality Measures'' section (III.A.3) later in the preamble for a more detailed discussion of the CQM certification criteria. Please also see the EHR Incentive Programs Stage 3 proposed rule published elsewhere in this issue of the **Federal Register** for proposals related to CQMs, including the CEHRT definition proposal.
- It includes the 2015 Edition ''smoking status,'' ''implantable device list,'' and ''application access to Common Clinical Data Set'' certification criteria. For a detailed discussion of these certification criteria, please refer to section III.A.3 of the preamble.
- It includes the proposed 2015 Edition certification criteria that correspond to the remaining 2014 Edition certification criteria referenced in the ''2014 Edition'' Base EHR definition (*i.e.,* Computerized Provider Order Entry (CPOE), demographics, problem list, medication list, medication allergy list, clinical decision support (CDS), transitions of care, data portability, and relevant transport certification criteria). On the inclusion of transport certification criteria, we propose to include the ''Direct Project'' criterion (§ 170.315(h)(1)) as well as the ''Direct Project, Edge Protocol and XDR/XDM'' [1] criterion (§ 170.315(h)(2)) as equivalent alternative means for meeting the 2015 Edition Base EHR definition for the reasons discussed under ''Transport Methods and Other Protocols'' in section III.A.3 of the preamble.

We refer readers to section III.B.1 for a more detailed discussion of the proposed 2015 Edition Base EHR definition.

b. CEHRT Definition

We propose to remove the Certified EHR Technology (CEHRT) definition from § 170.102 for the following reasons. The CEHRT definition has always been defined in a manner that supports the EHR Incentive Programs. As such, the CEHRT definition would more appropriately reside solely within the EHR Incentive Programs regulations. This would also be consistent with our approach in this proposed rule to make the ONC Health IT Certification Program more open and accessible to other types of health IT beyond EHR technology and for health IT that supports care and practice settings beyond those included in the EHR Incentive Programs. Further, this approach should add administrative simplicity in that regulatory provisions, which EHR Incentive Programs participants must meet (*e.g.,* the CEHRT definition), would be defined within the context of rulemakings for those programs. We understand that the CEHRT definition proposed by CMS would continue to include the Base EHR definition(s) defined by ONC, including the 2015 Edition Base EHR definition proposed in this proposed rule. We also refer readers to Table 2 (''2015 Edition Proposed Certification Criteria Associated with the EHR Incentive Programs Stage 3'') found in section III.A.3 of this preamble. Table 2 crosswalks proposed 2015 Edition certification criteria with the proposed CEHRT definition and proposed EHR Incentive Programs Stage 3 objectives.

c. Common Clinical Data Set

We propose to revise the ''Common MU Data Set'' definition in § 170.102. We propose to change the name to ''Common Clinical Data Set,'' which aligns with our approach throughout this proposed rule to make the ONC Health IT Certification Program more open and accessible to other types of health IT beyond EHR technology and for health IT that supports care and practice settings beyond those included in the EHR Incentive Programs. We also propose to change references to the ''Common MU Data Set'' in the 2014 Edition (§ 170.314) to ''Common Clinical Data Set.''

We propose to revise the definition to account for the new and updated standards and code sets we propose to adopt in this proposed rule that would improve and advance interoperability through the exchange of the Common Clinical Data Set. We also propose to revise the definition to support patient safety through clearly referenced data elements and the inclusion of new patient data. These proposed revisions would *not* change the standards, codes sets, and data requirements specified in the Common Clinical Data Set for 2014 Edition certification. They would only apply to health IT certified to the 2015 Edition Health IT certification criteria that reference the Common Clinical Data Set.

3. The ONC Health IT Certification Program and Health IT Module

We propose to change the name of the ONC HIT Certification Program to the ''ONC Health IT Certification Program'' (referred to as the ''ONC Health IT Certification Program'' throughout this proposed rule). We also propose to modify the ONC Health IT Certification Program in ways that would further open access to other types of health IT beyond EHR technology and for health IT that supports care and practice settings beyond the ambulatory and inpatient settings. These modifications would also serve to support other public and private programs that may reference the use of health IT certified under the ONC Health IT Certification Program. When we established the certification

[1] XDR stands for Cross-Enterprise Document Reliable Interchange. XDM stands for Cross-Enterprise Document Media Interchange.

program (76 FR 1294), we stated our initial focus would be on EHR technology and supporting the EHR Incentive Programs, which focus on the ambulatory setting and inpatient setting. Our proposals in this proposed rule would permit other types of health IT (*e.g.,* laboratory information systems (LISs)), and technology implemented by health information service providers (HISPs) and health information exchanges (HIEs)) to receive appropriate attribution and not be referenced by a certificate with ''EHR'' in it. Our proposals also support health IT certification for other care and practice settings such as long-term post-acute care (LTPAC), behavioral health, and pediatrics. Further, the proposals in this rule would make it simpler for certification criteria and certified health IT to be referenced by other HHS programs (*e.g.,* Medicaid and Medicare payment programs and various grant programs), other public programs, and private entities and associations.

As part of our approach to evolve the ONC Health IT Certification Program, we have replaced prior rulemaking use of ''EHR'' and ''EHR technology'' with ''health IT.'' The term health IT is reflective of the scope of ONC's authority under the Public Health Service Act (§ 3000(5) as ''health information technology'' is so defined), and represents a broad range of technology, including EHR technology. It also more properly represents some of the technology, as noted above, that has been previously certified to editions of certification criteria under the ONC Health IT Certification Program and may be certified to the proposed 2015 Edition in the future. Similarly, to make the ONC Health IT Certification Program more open and accessible, we propose to rename the EHR Module as ''Health IT Module'' and will use this term throughout the proposed rule.

We propose *not* to require ONC-Authorized Certification Bodies (ACBs) to certify all Health IT Modules to the 2015 Edition ''meaningful use measurement'' certification criteria (§ 170.315(g)(1) ''automated numerator recording'' and § 170.315(g)(2) ''automated measure calculation''). We note that *CMS has proposed* to include the 2015 Edition ''meaningful use measurement'' certification criteria in the CEHRT definition as a unique program requirement for the EHR Incentive Programs.

We propose a new, simpler, straight-forward approach to privacy and security certification requirements for Health IT Modules certified to the 2015 Edition. In essence, we identify the privacy and security certification criteria that would be applicable to a Health IT Module presented for certification based on the other capabilities included in the Health IT Module and for which certification is sought. Under the proposed approach, a health IT developer would know exactly what it needed to do in order to get its Health IT Module certified and a purchaser of a Health IT Module would know exactly what privacy and security functionality against which the Health IT Module had to be tested in order to be certified.

We propose new and revised principles of proper conduct (PoPC) for ONC–ACBs. We propose to require ONC–ACBs to report an expanded set of information to ONC for inclusion in the open data file that would make up the Certified Health IT Product List (CHPL). We propose to revise the PoPC in order to provide for more meaningful disclosure of certain types of costs and limitations that could interfere with the ability of users to implement certified health IT in a manner consistent with its certification. We propose that ONC–ACBs retain records longer and consistent with industry standards. We propose to require that ONC–ACBs obtain a record of all adaptations and updates, including changes to user-facing aspects, made to certified health IT, on a monthly basis each calendar year. We propose to require that ONC–ACBs report to the National Coordinator complaints received on certified health IT. We propose to adopt new requirements for ''in-the-field'' surveillance under the ONC Health IT Certification Program that would build on ONC–ACBs' existing surveillance responsibilities by specifying requirements and procedures for in-the-field surveillance. We believe these proposed new and revised PoPC would promote greater transparency and accountability for the ONC Health IT Certification Program. We also include a request for comment on the potential ''decertification'' of health IT that proactively blocks the sharing of information.

C. Costs and Benefits

Our estimates indicate that this proposed rule is an economically significant rule as its overall costs for health IT developers may be greater than $100 million in at least one year. We have, therefore, projected the costs and benefits of the proposed rule. The estimated costs expected to be incurred by health IT developers to develop and prepare health IT to be tested and certified in accordance with the 2015 Edition health IT certification criteria (and the standards and implementation specifications they include) are represented in monetary terms in Table 1 below. We note that this proposed rule does not impose the costs cited as compliance costs, but rather as investments which health IT developers voluntarily take on and expect to recover with an appropriate rate of return.

The dollar amounts expressed in Table 1 are expressed in 2013 dollars.

TABLE 1—DISTRIBUTED TOTAL DEVELOPMENT AND PREPARATION COSTS FOR HEALTH IT DEVELOPERS (4-YEAR PERIOD)—TOTALS ROUNDED

Year	Ratio (%)	Total low cost estimate ($M)	Total high cost estimate ($M)	Total average cost estimate ($M)
2015	25	49.36	101.80	75.58
2016	30	59.23	122.16	90.70
2017	30	59.23	122.16	90.70
2018	15	29.61	61.08	45.35
4-Year Totals		197.43	407.20	302.32

We believe that there will be several significant benefits that may arise from this proposed rule for patients, health care providers, and health IT developers. The 2015 Edition continues to improve health IT interoperability through the adoption of new and updated standards and implementation specifications. For example, many

proposed certification criteria include standards and implementation specifications for interoperability that directly support the EHR Incentive Programs, which include objectives and measures for the interoperable exchange of health information and for providing patients electronic access to their health information in structured formats. In addition, proposed certification criteria that support the collection of patient data that could be used to address health disparities would not only benefit patients, but the entire health care delivery system through improved quality of care. The 2015 Edition also supports usability and patient safety through new and enhanced certification requirements for health IT.

Our proposals to make the ONC Health IT Certification Program open and accessible to more types of health IT and for health IT that supports a variety of care and practice settings should benefit health IT developers, providers practicing in other care/practice settings, and consumers through the availability and use of certified health IT that includes capabilities that promote interoperability and enhanced functionality.

II. Background

A. Statutory Basis

The Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (the Recovery Act) (Pub. L. 111–5), was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act (PHSA) and created ''Title XXX—Health Information Technology and Quality'' (Title XXX) to improve health care quality, safety, and efficiency through the promotion of HIT and electronic health information exchange.

1. Standards, Implementation Specifications, and Certification Criteria

The HITECH Act established two new federal advisory committees, the Health IT Policy Committee (HITPC) and the Health IT Standards Committee (HITSC) (sections 3002 and 3003 of the PHSA, respectively). Each is responsible for advising the National Coordinator for Health Information Technology (National Coordinator) on different aspects of standards, implementation specifications, and certification criteria. The HITPC is responsible for, among other duties, recommending priorities for the development, harmonization, and recognition of standards, implementation specifications, and certification criteria. Main responsibilities of the HITSC include recommending standards, implementation specifications, and certification criteria for adoption by the Secretary under section 3004 of the PHSA, consistent with the ONC-coordinated Federal Health IT Strategic Plan.

Section 3004 of the PHSA identifies a process for the adoption of health IT standards, implementation specifications, and certification criteria and authorizes the Secretary to adopt such standards, implementation specifications, and certification criteria. As specified in section 3004(a)(1), the Secretary is required, in consultation with representatives of other relevant federal agencies, to jointly review standards, implementation specifications, and certification criteria endorsed by the National Coordinator under section 3001(c) and subsequently determine whether to propose the adoption of any grouping of such standards, implementation specifications, or certification criteria. The Secretary is required to publish all determinations in the **Federal Register**.

Section 3004(b)(3) of the PHSA titled, Subsequent Standards Activity, provides that the Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent with the schedule published by the HITSC. We consider this provision in the broader context of the HITECH Act to grant the Secretary the authority and discretion to adopt standards, implementation specifications, and certification criteria that have been recommended by the HITSC and endorsed by the National Coordinator, as well as other appropriate and necessary health IT standards, implementation specifications, and certification criteria. Throughout this process, the Secretary intends to continue to seek the insights and recommendations of the HITSC.

2. Health IT Certification Programs

Section 3001(c)(5) of the PHSA provides the National Coordinator with the authority to establish a certification program or programs for the voluntary certification of health IT. Specifically, section 3001(c)(5)(A) specifies that the National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this subtitle (*i.e.,* certification criteria adopted by the Secretary under section 3004 of the PHSA).

The certification program(s) must also include, as appropriate, testing of the technology in accordance with section 13201(b) of the [HITECH] Act. Overall, section 13201(b) of the HITECH Act requires that with respect to the development of standards and implementation specifications, the Director of the National Institute of Standards and Technology (NIST), in coordination with the HITSC, shall support the establishment of a conformance testing infrastructure, including the development of technical test beds. The HITECH Act also indicates that the development of this conformance testing infrastructure may include a program to accredit independent, non-Federal laboratories to perform testing.

B. Regulatory History

1. Standards, Implementation Specifications, and Certification Criteria Rules

The Secretary issued an interim final rule with request for comments titled, ''Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology'' (75 FR 2014, Jan. 13, 2010) (the ''S&CC January 2010 interim final rule''), which adopted an initial set of standards, implementation specifications, and certification criteria. After consideration of the public comments received on the S&CC January 2010 interim final rule, a final rule was issued to complete the adoption of the initial set of standards, implementation specifications, and certification criteria and realign them with the final objectives and measures established for the EHR Incentive Programs Stage 1 (formally titled: Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule, (75 FR 44590, July 28, 2010) and referred to as the ''2011 Edition final rule''). The 2011 Edition final rule also established the first version of the Certified EHR Technology (CEHRT) definition. Subsequent to the 2011 Edition final rule (October 13, 2010), we issued an interim final rule with a request for comment to remove certain implementation specifications related to public health surveillance that had been previously adopted in the 2011 Edition final rule (75 FR 62686).

The standards, implementation specifications, and certification criteria

adopted by the Secretary in the 2011 Edition final rule established the capabilities that CEHRT must include in order to, at a minimum, support the achievement of EHR Incentive Programs Stage 1 by EPs, eligible hospitals, and CAHs under the EHR Incentive Programs Stage 1 final rule (the ''EHR Incentive Programs Stage 1 final rule'') (see 75 FR 44314 for more information about meaningful use and the Stage 1 requirements).

The Secretary issued a proposed rule with request for comments titled ''Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology'' (77 FR 13832, March 7, 2012) (the ''2014 Edition proposed rule''), which proposed new and revised standards, implementation specifications, and certification criteria. After consideration of the public comments received on the 2014 Edition proposed rule, a final rule was issued to adopt the 2014 Edition set of standards, implementation specifications, and certification criteria and realign them with the final objectives and measures established for the EHR Incentive Programs Stage 2 as well as Stage 1 revisions (Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology (77 FR 54163, Sept. 4, 2012) (the ''2014 Edition final rule''). The standards, implementation specifications, and certification criteria adopted by the Secretary in the 2014 Edition final rule established the capabilities that CEHRT must include in order to, at a minimum, support the achievement of the EHR Incentive Programs Stage 2 by EPs, eligible hospitals, and CAHs under the EHR Incentive Programs Stage 2 final rule (the ''EHR Incentive Programs Stage 2 final rule'') (see 77 FR 53968 for more information about the EHR Incentive Programs Stage 2 requirements).

On December 7, 2012, an interim final rule with a request for comment was jointly issued and published by ONC and CMS to update certain standards that had been previously adopted in the 2014 Edition final rule. The interim final rule also revised the EHR Incentive Programs by adding an alternative measure for the Stage 2 objective for hospitals to provide structured electronic laboratory results to ambulatory providers, corrected the regulation text for the measures associated with the objective for hospitals to provide patients the ability to view online, download, and transmit information about a hospital admission, and made the case number threshold exemption policy for clinical quality measure (CQM) reporting applicable for eligible hospitals and CAHs beginning with FY 2013. The rule also provided notice of CMS's intent to issue technical corrections to the electronic specifications for CQMs released on October 25, 2012 (77 FR 72985). On September 4, 2014, a final rule (Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program for 2014 and Other Changes to the EHR Incentive Program; and Health Information Technology: Revisions to the Certified EHR Technology Definition and EHR Certification Changes Related to Standards; Final Rule) (79 FR 52910) was published adopting these proposals.

On November 4, 2013, the Secretary published an interim final rule with a request for comment, 2014 Edition Electronic Health Record Certification Criteria: Revision to the Definition of ''Common Meaningful Use (MU) Data Set'' (78 FR 65884), to make a minor revision to the Common MU Data Set definition. This revision was intended to allow more flexibility with respect to the representation of dental procedures data for EHR technology testing and certification.

On February 26, 2014, the Secretary published a proposed rule titled ''Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements'' (79 FR 10880) (''Voluntary Edition proposed rule''). The proposed rule proposed a voluntary edition of certification criteria that was designed to enhance interoperability, promote innovation, and incorporate ''bug fixes'' to improve upon the 2014 Edition. A correction notice was published for the Voluntary Edition proposed rule on March 19, 2014, entitled ''Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements; Correction'' (79 FR 15282). This correction notice corrected the preamble text and gap certification table for four certification criteria that were omitted from the list of certification criteria eligible for gap certification for the 2015 Edition EHR certification criteria. On September 11, 2014, a final rule was published titled ''2014 Edition Release 2 Electronic Health Record (EHR) Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange'' (79 FR 54430) (''2014 Edition Release 2 final rule''). The final rule adopted a small subset of the original proposals in the Voluntary Edition proposed rule as optional and revised 2014 Edition EHR certification criteria that provide flexibility, clarity, and enhance health information exchange. It also finalized administrative proposals (*i.e.,* removal of regulatory text from the Code of Federal Regulations (CFR)) and proposals for the ONC HIT Certification Program that provide improvements.

On May 23, 2014, CMS and ONC jointly published the ''Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record Incentive Programs for 2014; and Health Information Technology: Revisions to the Certified EHR Technology Definition'' proposed rule (79 FR 29732). The rule proposed to update the EHR Incentive Programs Stage 2 and Stage 3 participation timeline. It proposed to revise the CEHRT definition to permit the use of EHR technology certified to the 2011 Edition to meet the CEHRT definition for FY/CY 2014. It also proposed to allow EPs, eligible hospitals, and CAHs that could not fully implement EHR technology certified to the 2014 Edition for an EHR reporting period in 2014 due to delays in the availability of such technology to continue to use EHR technology certified to the 2011 Edition or a combination of EHR technology certified to the 2011 Edition and 2014 Edition for the EHR reporting periods in CY 2014 and FY 2014. On September 4, 2014, a final rule (''CEHRT Flexibility final rule'') was published (79 FR 52910) adopting these proposals.

2. Medicare and Medicaid EHR Incentive Programs Rules

On January 13, 2010, CMS published the EHR Incentive Programs Stage 1 proposed rule (75 FR 1844). The rule proposed the criteria for Stage 1 of the EHR Incentive Programs and regulations associated with the incentive payments made available under Division B, Title IV of the HITECH Act. Subsequently, CMS published a final rule (75 FR 44314) for Stage 1 and the EHR Incentive Programs on July 28, 2010, simultaneously with the publication of the 2011 Edition final rule. The EHR Incentive Programs Stage 1 final rule established the objectives, associated measures, and other requirements that EPs, eligible hospitals, and CAHs must satisfy to meet Stage 1.

On March 7, 2012, CMS published the EHR Incentive Programs Stage 2

proposed rule (77 FR 13698). Subsequently, CMS published a final rule (77 FR 53968) for the EHR Incentive Programs on Sept. 4, 2012, simultaneously with the publication of the 2014 Edition final rule. The EHR Incentive Programs Stage 2 final rule established the objectives, associated measures, and other requirements that EPs, eligible hospitals, and CAHs must satisfy to meet Stage 2 as well as revised some Stage 1 requirements.

As described above in Section II.B.1, ONC and CMS jointly issued an interim final rule with a request for comment that was published on December 7, 2012 and a final rule that published on September 4, 2014. Also, as described above in Section II.B.1, ONC and CMS jointly issued proposed and final rules that were published on May 23, 2014 and September 4, 2014, respectively.

3. ONC Health IT Certification Program Rules

On March 10, 2010, ONC published a proposed rule (75 FR 11328) titled, ''Proposed Establishment of Certification Programs for Health Information Technology'' (the ''Certification Programs proposed rule''). The rule proposed both a temporary and permanent certification program for the purposes of testing and certifying HIT. It also specified the processes the National Coordinator would follow to authorize organizations to perform the certification of HIT. A final rule establishing the temporary certification program was published on June 24, 2010 (75 FR 36158) (''Temporary Certification Program final rule'') and a final rule establishing the permanent certification program was published on January 7, 2011 (76 FR 1262) (''the Permanent Certification Program final rule'').

On May 31, 2011, ONC published a proposed rule (76 FR 31272) titled ''Permanent Certification Program for Health Information Technology; Revisions to ONC-Approved Accreditor Processes.'' The rule proposed a process for addressing instances where the ONC–Approved Accreditor (ONC–AA) engaged in improper conduct or did not perform its responsibilities under the permanent certification program, addressed the status of ONC-Authorized Certification Bodies in instances where there may be a change in the accreditation organization serving as the ONC–AA, and clarified the responsibilities of the new ONC–AA. All these proposals were finalized in a final rule published on November 25, 2011 (76 FR 72636).

The 2014 Edition final rule made changes to the permanent certification program. The final rule adopted a proposal to change the Permanent Certification Program's name to the ''ONC HIT Certification Program,'' revised the process for permitting the use of newer versions of ''minimum standard'' code sets, modified the certification processes ONC–ACBs need to follow for certifying EHR Modules in a manner that provides clear implementation direction and compliance with the new certification criteria, and eliminated the certification requirement that every EHR Module be certified to all the mandatory ''privacy and security'' certification criteria.

The Voluntary Edition proposed rule included proposals that focused on improving regulatory clarity, simplifying the certification of EHR Modules that are designed for purposes other than meeting Meaningful Use requirements, and discontinuing the use of the Complete EHR definition. As noted above, we issued the 2014 Edition Release 2 final rule to complete the rulemaking for the Voluntary Edition proposed rule. The 2014 Edition Release 2 final rule discontinued the ''Complete EHR'' certification concept beginning with the proposed 2015 Edition, adopted an updated standard (ISO/IEC 17065) for the accreditation of ONC–ACBs, and adopted the ''ONC Certified HIT'' certification and design mark for required use by ONC–ACBs under the ONC Health IT Certification Program.

III. Provisions of the Proposed Rule Affecting Standards, Implementation Specifications, and Certification Criteria

A. 2015 Edition Health IT Certification Criteria

This rule proposes new, revised, and unchanged certification criteria that would establish the capabilities and related standards and implementation specifications for the certification of health IT, including EHR technology. We refer to these new, revised, and unchanged certification criteria as the ''2015 Edition health IT certification criteria'' and propose to add this term and its definition to § 170.102. As noted in the Executive Summary, we also refer to these criteria as the ''2015 Edition'' in this preamble. We propose to codify the 2015 Edition in § 170.315 to set them apart from other editions of certification criteria and make it easier for stakeholders to quickly determine the certification criteria the 2015 Edition includes.

Health IT certified to these proposed certification criteria and associated standards and implementation specifications could be implemented as part of an EP's, eligible hospital's, or CAH's CEHRT and used to demonstrate meaningful use (as identified in Table 2 below). We note that Table 2 does *not* identify certification criteria that are included in conditional certification requirements, such as privacy and security, safety-enhanced design, and quality management system certification criteria. We do, however, classify these types of certification criteria as ''associated'' with the EHR Incentives Programs Stage 3 for the purposes of the regulatory impact analysis we performed for this proposed rule (see section VIII.B.1).

Health IT certified to the proposed certification criteria and associated standards and implementation specifications could also be used to meet other HHS program requirements (*e.g.*, grant and contract requirements) or referenced by private sector associations and entities.

TABLE 2—2015 EDITION PROPOSED CERTIFICATION CRITERIA ASSOCIATED WITH THE EHR INCENTIVE PROGRAMS STAGE 3

Proposed CFR citation	Certification criterion	Proposed inclusion in 2015 edition base EHR definition	Relationship to the proposed CEHRT [2] definition and proposed stage 3 objectives
§ 170.315(a)(1)	Computerized Provider Order Entry (CPOE)—medications.	Included [3]	Objective 4.
§ 170.315(a)(2)	CPOE—laboratory	Included [4]	Objective 4.
§ 170.315(a)(3)	CPOE—diagnostic imaging	Included [5]	Objective 4.

TABLE 2—2015 EDITION PROPOSED CERTIFICATION CRITERIA ASSOCIATED WITH THE EHR INCENTIVE PROGRAMS STAGE 3—Continued

Proposed CFR citation	Certification criterion	Proposed inclusion in 2015 edition base EHR definition	Relationship to the proposed CEHRT [2] definition and proposed stage 3 objectives
§ 170.315(a)(4)	Drug-drug, Drug-allergy Interaction Checks for CPOE.	Not included	Objective 3.
§ 170.315(a)(5)	Demographics	Included	No additional relationship beyond the Base EHR definition.
§ 170.315(a)(7)	Problem List	Included	No additional relationship beyond the Base EHR definition.
§ 170.315(a)(8)	Medication List	Included	No additional relationship beyond the Base EHR definition.
§ 170.315(a)(9)	Medication Allergy List	Included	No additional relationship beyond the Base EHR definition.
§ 170.315(a)(10)	Clinical Decision Support	Included	Objective 3.
§ 170.315(a)(11)	Drug-formulary and Preferred Drug List Checks.	Not included	Objective 2.
§ 170.315(a)(12)	Smoking Status	Included	No additional relationship beyond the Base EHR definition.
§ 170.315(a)(14)	Family Health History	Not included	CEHRT [6].
§ 170.315(a)(15)	Family Health History—pedigree	Not included	CEHRT [7].
§ 170.315(a)(17)	Patient-specific Education Resources	Not included	Objective 5.
§ 170.315(a)(19)	Patient Health Information Capture	Not included	CEHRT Objective 6.
§ 170.315(a)(20)	Implantable Device List	Included	No additional relationship beyond the Base EHR definition.
§ 170.315(b)(1)	Transitions of Care	Included	Objective 7.
§ 170.315(b)(2)	Clinical Information Reconciliation and Incorporation.	Not included	Objective 7.
§ 170.315(b)(3)	Electronic Prescribing	Not included	Objective 2.
§ 170.315(b)(6)	Data Portability	Included	No additional relationship beyond the Base EHR definition.
§ 170.315(c)(1) [8]	Clinical Quality Measures—record and export.	Included	CEHRT.
§ 170.315(e)(1)	View, Download, and Transmit to Third Party.	Not included	Objective 5 Objective 6.
§ 170.315(e)(2)	Secure Messaging	Not included	Objective 6.
§ 170.315(f)(1)	Transmission to Immunization Registries.	Not included	Objective 8.[9]
§ 170.315(f)(2)	Transmission to Public Health Agencies—syndromic surveillance.	Not included	Objective 8.
§ 170.315(f)(3)	Transmission to Public Health Agencies—reportable laboratory tests and values/results.	Not included	Objective 8.
§ 170.315(f)(4)	Transmission to Cancer Registries	Not included	Objective 8.
§ 170.315(f)(5)	Transmission to Public Health Agencies—case reporting.	Not included	Objective 8.
§ 170.315(f)(6)	Transmission to Public Health Agencies—antimicrobial use and resistance reporting.	Not included	Objective 8.
§ 170.315(f)(7)	Transmission to Public Health Agencies—health care surveys.	Not included	Objective 8.
§ 170.315(g)(1)	Automated Numerator Recording	Not included	CEHRT.
§ 170.315(g)(2)	Automated Measure Calculation	Not included	CEHRT.
§ 170.315(g)(7)	Application Access to Common Clinical Data Set.	Included	Objective 5 Objective 6.
§ 170.315(h)(1)	Direct Project	Included [10]	No additional relationship beyond the Base EHR definition.
§ 170.315(h)(2)	Direct Project, Edge Protocol, and XDR/XDM.	Included [11]	No additional relationship beyond the Base EHR definition.

[2] CMS' CEHRT definition would include the criteria adopted in the Base EHR definition. For more details on the CEHRT definition, please see the CMS EHR Incentive Programs proposed rule published elsewhere in this issue of the **Federal Register**.
[3] Technology needs to be certified to § 170.315(a)(1), (a)(2), or (a)(3).
[4] Technology needs to be certified to § 170.315(a)(1), (a)(2), or (a)(3).
[5] Technology needs to be certified to § 170.315(a)(1), (a)(2), or (a)(3).
[6] Technology needs to be certified to § 170.315(a)(14) or (a)(15).
[7] Technology needs to be certified to § 170.315(a)(14) or (a)(15).
[8] As discussed in the preamble for the "clinical quality measures—report" criterion, additional CQM certification policy may be proposed in or with CMS payment rules in CY15. As such, additional CQM certification criteria may be proposed for the Base EHR and/or CEHRT definitions.
[9] For the public health certification criteria in § 170.315(f), technology would only need to be certified to those criteria that are required to meet the options the provider intends to report in order to meet the proposed Objective 8: Public Health and Clinical Data Registry Reporting.
[10] Technology needs to be certified to § 170.315(h)(1) or (h)(2) to meet the proposed Base EHR definition.
[11] Technology needs to be certified to § 170.315(h)(1) or (h)(2) to meet the proposed Base EHR definition.

1. Applicability

Section 170.300 establishes the applicability of subpart C—Certification Criteria for Health Information Technology. We propose to revise paragraph (d) of § 170.300 to add in a reference to § 170.315 and revise the parenthetical in the paragraph to say ''*i.e.,* apply to any health care setting'' instead of ''*i.e.,* apply to both ambulatory and inpatient settings.'' These proposed revisions would clarify which specific capabilities *within* a certification criterion included in § 170.315 have general applicability (*i.e.,* apply to any health care setting) or apply only to an inpatient setting or an ambulatory setting. The proposed revision to change the language of the parenthetical aligns with our proposed approach to make the ONC Health IT Certification Program more agnostic to health care settings and accessible to health IT that supports care and practice settings beyond the ambulatory and inpatient settings. We refer readers to section IV.B of this preamble for a detailed discussion of our proposals to modify the ONC Health IT Certification Program.

We note that, with the proposed 2015 Edition, we no longer label certification criteria as either optional or ambulatory/inpatient (at the second paragraph level). For example, the proposed 2015 Edition certification criterion for electronic medication administration record is simply ''electronic medication administration record'' instead of ''inpatient setting only—electronic medication administration record.'' Similarly, the proposed 2015 Edition certification criterion for ''accounting of disclosures'' is simply ''accounting of disclosures'' instead of ''optional—accounting of disclosures.'' These simplifications are possible given that, beginning with the 2015 Edition health IT certification criteria, ''Complete EHR'' certifications will no longer be issued (see 79 FR 54443–45). Therefore, there is no longer a need to designate an entire certification criterion in this manner. Again, this approach supports our goal to make the ONC Health IT Certification Program more agnostic to health care settings and accessible to health IT that supports care and practice settings beyond the ambulatory and inpatient settings.

We propose to replace the term ''EHR technology'' in paragraphs (d)(1) and (d)(2) with ''health IT'' to align with our proposed approach to make the ONC Health IT Certification Program more clearly open to the certification of all types of health IT. Again, we refer readers to section IV.B of this preamble for a detail discussion of our proposals to modify the ONC Health IT Certification Program.

2. Standards and Implementation Specifications

a. National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act (NTTAA) of 1995 (15 U.S.C. § 3701 et. seq.) and the Office of Management and Budget (OMB) Circular A–119 [12] require the use of, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. The NTTAA and OMB Circular A–119 provide exceptions to selecting only standards developed or adopted by voluntary consensus standards bodies, namely when doing so would be inconsistent with applicable law or otherwise impractical. In this proposed rule, we refer to voluntary consensus standards, except for:

- The standards adopted in § 170.202. (These standards were developed by groups of industry stakeholders committed to advancing the Direct Project,[13] which included initiatives under the Standards and Interoperability (S&I) Framework.[14] These groups used consensus processes similar to those used by other industry stakeholders and voluntary consensus standards bodies.);
- The standards we propose to adopt at § 170.205(a)(5)(iii) and (iv) for electronic submission medical documentation (esMD) (These standards were developed by groups of industry stakeholders committed to advancing esMD,[15] which included initiatives under the Standards and Interoperability (S&I) Framework.[16] These groups used consensus processes similar to those used by other industry stakeholders and voluntary consensus standards bodies.);
- The standards we propose to adopt at § 170.205(d)(4) and (e)(4) for reporting of syndromic surveillance and immunization information to public health agencies, respectively (These standards go through a process similar within the public health community to those used by other industry stakeholders and voluntary consensus standards bodies.);
- The standard we propose to adopt at § 170.207(f)(2) for race and ethnicity; and
- Certain standards related to the protection of electronic health information adopted in § 170.210.

We are aware of no voluntary consensus standard that would serve as an alternative to these standards for the purposes that we have identified in this proposed rule.

b. Compliance With Adopted Standards and Implementation Specifications

In accordance with Office of the Federal Register regulations related to ''incorporation by reference,'' 1 CFR part 51, which we follow when we adopt proposed standards and/or implementation specifications in any subsequent final rule, the entire standard or implementation specification document is deemed published in the **Federal Register** when incorporated by reference therein with the approval of the Director of the Federal Register. Once published, compliance with the standard and implementation specification includes the entire document unless we specify otherwise. For example, if we adopted the HL7 Laboratory Orders Interface (LOI) implementation guide (IG) proposed in this proposed rule, health IT certified to certification criteria referencing this IG would need to demonstrate compliance with all mandatory elements and requirements of the IG. If an element of the IG is optional or permissive in any way, it would remain that way for testing and certification unless we specified otherwise in regulation. In such cases, the regulatory text would preempt the permissiveness of the IG.

c. ''Reasonably Available'' to Interested Parties

The Office of the Federal Register has established new requirements for materials (*e.g.,* standards and implementation specifications) that agencies propose to incorporate by reference in the **Federal Register** (79 FR 66267; 1 CFR 51.5(a)). To comply with these requirements, in section VI (''Incorporation by Reference'') of this preamble, we provide summaries of, and uniform resource locators (URLs) to, the standards and implementation specifications we propose to adopt and subsequently incorporate by reference in the **Federal Register**. To note, we also provide relevant information about

[12] *http://www.whitehouse.gov/omb/circulars_a119.*

[13] *http://www.healthit.gov/policy-researchers-implementers/direct-project.*

[14] *http://www.healthit.gov/policy-researchers-implementers/standards-interoperability-si-framework.*

[15] *http://wiki.siframework.org/esMD+-+Author+of+Record* and *http://wiki.siframework.org/esMD+-+Provider+Profiles+Authentication.*

[16] *http://www.healthit.gov/policy-researchers-implementers/standards-interoperability-si-framework.*

these standards and implementation specifications throughout this section of the preamble (section III), including URLs.

d. ''Minimum Standards'' Code Sets

We propose to adopt newer versions of four previously adopted minimum standards code sets in this proposed rule for the 2015 Edition. These code sets are the September 2014 Release of the U.S. Edition of SNOMED CT®, LOINC® version 2.50, the February 2, 2015 monthly version of RxNorm, and the February 2, 2015 version of the CVX code set. We also propose to adopt two new minimum standards code sets (the National Drug Codes (NDC)—Vaccine Codes, updates through January 15, 2015 and the ''Race & Ethnicity—CDC'' code system in the PHIN Vocabulary Access and Distribution System (VADS) Release 3.3.9 (June 17, 2011)). As we have previously articulated (77 FR 54170), the adoption of newer versions improve interoperability and health IT implementation, while creating little additional burden through the inclusion of new codes. As many of these minimum standards code sets are updated frequently throughout the year, we will consider whether it may be more appropriate to adopt a version of a minimum standards code set that is issued before we publish a final rule for this proposed rule. In making such determination, as we have done with these proposed versions of minimum standards code sets, we will give consideration to whether it includes any new substantive requirements and its effect on interoperability. If adopted, a newer version of a minimum standards code set would serve as the baseline for certification. As with all adopted minimum standards code sets, health IT can be certified to newer versions of the adopted baseline version minimum standards code sets for purposes of certification, unless the Secretary specifically prohibits the use of a newer version (see § 170.555 and 77 FR 54268).

e. Object Identifiers (OIDs) for Certain Code Systems

We are providing the following table of OIDs for certain code systems to assist health IT developers in the proper identification and exchange of health information coded to the vocabulary standards proposed in this proposed rule.

Code system OID	Code system name
2.16.840.1.113883.6.96	IHTSDO SNOMED CT.®
2.16.840.1.113883.6.1	LOINC.®
2.16.840.1.113883.6.88	RxNorm.
2.16.840.1.113883.12.292	HL7 Standard Code Set CVX-Vaccines Administered.
2.16.840.1.113883.6.69	National Drug Code Directory.
2.16.840.1.113883.6.8	Unified Code of Units of Measure (UCUM [17]).
2.16.840.1.113883.6.13	Code on Dental Procedures and Nomenclature (CDT).
2.16.840.1.113883.6.4	International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS).
2.16.840.1.113883.6.238	Race & Ethnicity—Centers for Disease Control and Prevention (CDC).
2.16.840.1.113883.6.316	Tags for Identifying Languages—Request for Comment (RFC) 5646 (preferred language).

f. Subpart B—Standards and Implementation Specifications for Health Information Technology

In § 170.200, we propose to remove term ''EHR Modules'' and add in its place ''Health IT Modules.'' In § 170.210, we propose to remove the term ''EHR technology'' and add in its place ''health IT.'' These proposals are consistent with our overall approach to this rulemaking as discussed in the Executive Summary.

3. Certification Criteria

We discuss the certification criteria that we propose to adopt as the 2015 Edition below. In a header for each criterion, we specify where the proposed certification criteria would be included in § 170.315. We discuss each certification criterion in the chronological order in which it would appear in the CFR. In other words, the preamble that follows will discuss the proposed certification criteria in § 170.315(a) first, then § 170.315(b), and so on.

We identify the certification criteria as new, revised, or unchanged in comparison to the 2014 Edition. In the 2014 Edition final rule we gave meaning to the terms ''new,'' ''revised,'' and ''unchanged'' to both describe the differences between the 2014 Edition certification criteria and the 2011 Edition certification criteria as well as establish what certification criteria in the 2014 Edition were eligible for gap certification (see 77 FR 54171, 54202, and 54248). Given that beginning with the 2015 Edition ''Complete EHR'' certifications will no longer be issued (see also 79 FR 54443–45) and that our proposals in this proposed rule to make the ONC Health IT Certification Program more open and accessible to other health care/practice settings, we propose to give new meaning to these terms for the purpose of a gap certification analysis.

- *''New''* certification criteria are those that as a whole only include capabilities never referenced in previously adopted certification criteria editions and to which a Health IT Module presented for certification to the 2015 Edition could have never previously been certified. As a counter example, the splitting of a 2014 Edition certification criterion into two criteria as part of the 2015 Edition would not make those certification criteria ''new'' for the purposes of a gap certification eligibility analysis.
- *''Revised''* certification criteria are those that include within them capabilities referenced in a previously adopted edition of certification criteria as well as changed or additional new capabilities; and to which a Health IT Module presented for certification to the 2015 Edition could *not* have been previously certified to all of the included capabilities.
- *''Unchanged''* certification criteria would be certification criteria that include the same capabilities as compared to prior certification criteria of adopted editions; and to which a Health IT Module presented for certification to the 2015 Edition could have been previously certified to all of the included capabilities.

We explain the proposed certification criteria and provide accompanying rationale for the proposed certification criteria, including citing the recommendations of the HITPC and HITSC, where appropriate. For 2015 Edition health IT certification criteria

[17] Copyright © 1998–2013, Regenstrief Institute, Inc. and the UCUM Organization. All rights reserved.

that have been revised in comparison to their 2014 Edition counterparts, we focus the discussion on any revisions and clarifications in comparison to the 2014 Edition version of the criteria. A revised 2015 Edition certification criterion would also include all the other capabilities that were included in the 2014 Edition version. For example, we propose to adopt a 2015 Edition ''drug-drug, drug-allergy interaction checks for CPOE'' certification criterion (§ 170.315(a)(4)) that is revised in comparison to the 2014 Edition ''drug-drug, drug-allergy interaction checks'' criterion (§ 170.314(a)(2)). We only discuss clarifications (*e.g.,* the criterion name change) and revisions we propose as part of the 2015 Edition ''drug-drug, drug-allergy interaction checks for CPOE'' certification criterion. However, the 2015 Edition criterion also includes all the other capabilities of the 2014 Edition ''drug-drug, drug allergy interaction checks'' criterion. We refer readers to § 170.315 of the proposed regulation text near the end of this document, which specifies all the capabilities included in each proposed 2015 Edition certification criterion.

We include an appendix (Appendix A) to this proposed rule, which provides a table with the following data for each proposed 2015 Edition certification criterion, as applicable: (1) Proposed CFR citation; (2) estimated development hours; (3) proposed privacy and security certification requirements (approach 1); [18] (4) conditional certification requirements (§ 170.550); (5) gap certification eligibility; (6) proposed inclusion in the 2015 Edition Base EHR definition; and (7) relationship to proposed Stage 3 of the EHR Incentive Programs, including the CEHRT definition.

We propose, and readers should interpret, that the following terms used in the proposed 2015 Edition have the same meanings we adopted in the 2014 Edition final rule (77 FR 54168–54169), in response to public comment: ''user,'' ''record,'' ''change,'' ''access,'' ''incorporate,'' ''create,'' and ''transmit,'' but apply to all health IT not just ''EHR technology.'' For the term ''incorporate,'' we also direct readers to the additional explanation we provided under the ''transitions of care'' certification criterion (77 FR 54218) in the 2014 Edition final rule and in the Voluntary Edition proposed rule (79 FR 10898). We propose that the scope of a 2015 Edition certification criterion is the same as the scope previously assigned to a 2014 Edition certification criterion (for further explanation, see the discussion at 77 FR 54168). That is, certification to proposed 2015 Edition health IT certification criteria at § 170.315 would occur at the second paragraph level of the regulatory section and encompass all paragraph levels below the second paragraph level. We also propose to continue to use the same specific descriptions for the different types of ''data summaries'' established in the 2014 Edition final rule (77 FR 54170–54171) for the proposed 2015 Edition health IT certification criteria (*i.e.,* ''export summary,'' ''transition of care/referral summary,'' ''ambulatory summary,'' and ''inpatient summary.'')

As with the adoption of the 2011 and 2014 editions of certification criteria (see the introductory text to §§ 170.302, 170.304, 170.306, and 170.314), all capabilities mentioned in certification criteria are expected to be performed electronically, unless otherwise noted. Therefore, we no longer include ''electronically'' in conjunction with each capability included in a certification criterion proposed under § 170.315 because the proposed introductory text to § 170.315 (which covers all the certification criteria included in the section) clearly states that health IT must be able to *electronically* perform the following capabilities in accordance with all applicable standards and implementation specifications adopted in the part.

• Computerized Provider Order Entry

In the 2014 Edition Release 2 final rule, we adopted separate computerized provider order entry (CPOE) certification criteria based on the clinical purpose (*i.e.,* medications, laboratory, and diagnostic imaging) (79 FR 54435–36). We propose to take the same approach for the 2015 Edition and propose to adopt three certification criteria for CPOE, as compared to a single criterion that would include combined functionality for all three clinical purposes (*e.g.,* § 170.314(a)(1)).

We request comment on whether we should specify, for the purposes of testing and certification to the 2015 Edition CPOE criteria, certain data elements that a Health IT Module must be able to include in a transmitted order. In particular, we request comment on whether a Health IT Module should be able to include any or all of the following data elements: secondary diagnosis codes; reason for order; and comment fields entered by the ordering provider, if they are provided to the ordering provider in their order entry screen. We also request comment on whether there are any other data elements that a Health IT Module should be able to include as part of an order for the purposes of testing and certification. We clarify, however, that any specific data requirements for a transmitted order that may be adopted in a final rule would only apply in the absence of a standard for testing and certification. As discussed below, we propose a laboratory order standard for the ambulatory setting. If we were to adopt this standard in a final rule, any potential required data elements for a transmitted order adopted in response to this proposal would not be made applicable to the ambulatory setting for the ''CPOE—laboratory'' certification criterion.

• *Computerized Provider Order Entry—Medications*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(1) (Computerized provider order entry—medications)

We propose to adopt a 2015 Edition CPOE certification criterion specific to medication ordering. This proposed criterion does not reference any standards or implementation specifications and is unchanged in comparison to the 2014 Edition CPOE—medications criterion adopted at § 170.314(a)(18).

• *Computerized Provider Order Entry—Laboratory*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(2) (Computerized provider order entry—laboratory)

We propose to adopt a 2015 Edition CPOE certification criterion specific to laboratory ordering that is revised in comparison to the CPOE—laboratory criterion adopted at § 170.314(a)(19) as well as § 170.314(a)(1).

We propose to adopt and include in this criterion, for the *ambulatory setting,* the HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders (LOI) from EHR, Draft Standard for Trial Use, Release 2—US Realm (''Release 2'').[19] Due to the absence of a consensus standard for the purpose of sending laboratory orders from EHRs to laboratories, this standard was developed in conjunction with laboratories representative of the industry, health IT developers, and

[18] Please see section IV.C.1 (''Privacy and Security'') for a detailed discussion of approach 1.

[19] *http://www.hl7.org/special/committees/projman/searchableproject index.cfm?action=edit&ProjectNumber=922* and *http://www.hl7.org/participate/online balloting.cfm?ref=nav#nonmember.* Access to the current draft of the LOI Release 2 IG is freely available for review during the public comment period by establishing an HL7 user account.

provider stakeholders through an open consensus-based process under the Standards and Interoperability Framework (S&I Framework). Release 1 of the standard was balloted and approved through HL7, a standards developing organization. Release 2 is currently under ballot reconciliation with HL7 and should be published in the next few months. Release 2 would:

- Implement common formats across US Realm IGs for consistent reader experience (*e.g.,* sequence of sections, formatting, layout, and terminology);
- Adopt HL7 version 2.8 fields developed to fill gaps identified in the development of Release 1;
- Include harmonized data type ''flavors'' for use across the US Realm Lab IGs;
- Introduce initial requirements for error reporting conditions and severity (hard/soft errors) and system/application acknowledgements;
- Harmonize data element usage and cardinality requirements with LOI Release 1, and the electronic Directory of Services (eDOS) IG;
- Incorporate US Lab Realm value sets developed for clarity and consistency across all laboratory IGs; and
- Use a new publication method for value sets that allows for precision usage at point of use and provides ''at a glance'' comprehensive usage at the field and component-level across all laboratory IGs; and synced with value set activities (HL7, VSAC, etc.).

Overall, we propose to adopt Release 2 of the standard because it addresses errors and ambiguities found in Release 1 and harmonizes requirements with other laboratory standards we propose to adopt in this proposed rule. Release 2 would also make implementation of the LOI IG clearer and more consistent for health IT developers and laboratories, as well as improve interoperability. We propose to adopt Release 2 at § 170.205(l)(1).

Commenters on the Voluntary Edition proposed rule noted that for optimal interoperability we need to also adopt the most recent version of the HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2, (also referred to as the ''electronic Directory of Services (eDOS) IG''), as it is the companion IG to the LOI IG. We agree with the commenters' assessment and propose to include the most recent version of the eDOS IG in this criterion for certification to all health care settings (*i.e.,* not confining it to only the ambulatory setting) and adopt it at § 170.205(l)(2). The most recent version of the eDOS IG will be Release 2, Version 1.2, which is scheduled to publish in the next few months. Release 2, Version 1.2 is currently under ballot reconciliation.[20] In general, the eDOS IG provides requirements and guidance for the delivery of an electronic Directory of Services (test compendium) from a laboratory (compendium producer) to an EHR or other system (compendium consumer) where it is used to produce electronic orders (LOI-conformant messages) for laboratory tests. Version 1.2 of the eDOS IG addresses errors and ambiguities in the prior version as well as harmonizes with Release 2 of the LOI IG.

We also propose, for the purposes of certification, to require a Health IT Module to be able to use, at a minimum, the version of Logical Observation Identifiers Names and Codes (LOINC®) adopted at § 170.207(c)(3) (version 2.50) as the vocabulary standard for laboratory orders. This is the most recent version of LOINC®. We refer readers to section III.A.2.d (''Minimum Standards'' Code Sets) for further discussion of our adoption of LOINC® as a minimum standards code set and our proposal to adopt version 2.50, or potentially a newer version if released before a subsequent final rule, as the baseline for certification to the 2015 Edition.

We note that the LOI Release 2 IG requires the information for a test requisition as specified in the Clinical Laboratory Improvement Amendments (CLIA), 42 CFR 493.1241(c)(1) through (c)(8), to be included in the content message. Therefore, inclusion of this standard for certification may also facilitate laboratory compliance with CLIA.

- *Computerized Provider Order Entry—Diagnostic Imaging*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(3) (Computerized provider order entry—diagnostic imaging)

We propose to adopt a 2015 Edition CPOE certification criterion specific to diagnostic imaging. This proposed criterion does not reference any standards or implementation specifications, and is unchanged in comparison to the 2014 Edition CPOE—diagnostic imaging criterion adopted at § 170.314(a)(20). To note, we also propose to adopt the title of ''diagnostic imaging,'' which is the title we gave to the 2014 Edition version of this certification criterion in the 2014 Edition Release 2 final rule (79 FR 54436).

- *Drug-Drug, Drug-Allergy Interaction Checks for CPOE*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(4) (Drug-drug, drug-allergy interaction checks for CPOE)

We propose to adopt a 2015 Edition ''drug-drug, drug-allergy interaction checks for CPOE'' certification criterion that is revised in comparison to the 2014 Edition ''drug-drug, drug-allergy interaction checks'' criterion (§ 170.314(a)(2)). We propose to clarify that the capabilities included in this criterion are focused on CPOE by including ''for CPOE'' in the title of this criterion.

We also propose to include in this criterion the capabilities to record user actions for drug-drug, drug-allergy interaction (DD/DAI) interventions and to enable a user to view the actions taken for DD/DAI interventions (also referred to as ''checks''). Specifically, we propose that a Health IT Module must be able to record at least one action taken and by whom in response to drug-drug or drug-allergy interaction checks. To be certified to this criterion, a Health IT Module (at a user's request) must also be able to generate either a human readable display or human readable report of actions taken and by whom in response to drug-drug or drug-allergy interaction checks.

We solicited comment in the Voluntary Edition proposed rule on whether health IT should be able to track (which means ''record'' and will be referred to as ''record'' throughout this preamble) provider (referred to as ''user'' for the purposes of this proposed certification criterion) actions for DD/DAI interventions, including recording if and when the user viewed, accepted, declined, ignored, overrode, or otherwise commented on the DD/DAI interventions. We received comments that supported recording user actions for DD/DAI interventions (79 FR 54449). We also received comments recommending that we consider including recording user actions in response to CDS interventions. We discuss those comments under the CDS certification criterion in this section (III.A.3) of the preamble.

We believe that recording user actions for DD/DAI interventions could assist with quality improvement and patient safety. While some commenters expressed concern that functionality for recording user actions would be

[20] *http://www.hl7.org/participate/onlineballoting.cfm?ref=nav#nonmember.* Access to the current draft of the eDOS IG, Release 2, Version 1.2 is freely available for review during the public comment period by establishing an HL7 user account.

burdensome to develop, we believe the potential benefits of improved care and reduced adverse events that can come from using such functionality and being able to subsequently analyze user actions for DD/DAI interventions outweighs the development burden. To provide health IT developers with flexibility and the opportunity to innovate, we have explicitly not specified the types of actions a Health IT Module must be able to record to meet this criterion. Health IT developers would need to simply demonstrate that their Health IT Module can record at least one user action for DD/DAI checks. For example, a Health IT Module could include the capability to record whether the user viewed, accepted, declined, ignored, overrode, provided a rationale or explanation for the action taken, took some other type of action not listed here or otherwise commented on the DD/DAI check. We solicit comment on whether we should focus this proposed requirement to record at least one user action taken for DD/DAI interventions on a subset of DD/DAI interventions, such as those of highest patient safety concern, and what sources we should consider for defining this subset.

We note, however, that we do not intend with this proposed requirement to infer a specific workflow or user interface in order to achieve conformance to this criterion. While appropriate documentation in accordance with clinical, safety, and system design best practices for these DD/DAI interventions is beyond the scope of certification for this criterion, we would encourage health IT developers to consider these best practices in developing this functionality and attempt to not interrupt a provider's workflow unnecessarily to meet this criterion. This criterion also does *not* propose to establish the uses for the ''user action'' information, whom should be able to view the information, or who could adjust the capability. Further, based on stakeholder feedback, there does not appear to be a consensus method or standard for characterizing the severity of patient DD/DAI reactions. Therefore, until the stakeholder community determines if there should be a set of methods, standards, or clinical guidelines for determining the severity of a patient DD/DAI reaction, we believe that users should determine these definitions for their organization and/or setting.

While this proposed certification criterion focuses on DD/DAI checking at the point when a user enters a computerized order, we believe that there are instances when a user should be aware of a patient's DD/DAI when new medications or medication allergies are entered into the patient record. Therefore, we strongly encourage health IT developers to build in functionality, including but not limited to clinical decision support, that would inform a user of new or updated DD/DAI when the medication or medication allergy lists are updated. We also seek comment on whether we should include this functionality in certification and whether this functionality should be included in an existing certification criterion (*e.g.,* medication list, medication allergy list, clinical decision support) or a standalone criterion.

- *Demographics*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(5) (Demographics)

We propose to adopt a 2015 Edition ''demographics'' certification criterion that is revised as described below in comparison to the 2014 Edition certification criterion (§ 170.314(a)(3)).

Sex

We propose that, for certification (and testing) to this criterion, health IT must be capable of recording sex in accordance with HL7 Version 3 (''AdministrativeGender'') and a nullFlavor value attributed as follows: male (M); female (F); and unknown (UNK). This proposal serves as another means of improving interoperability through the use of consistent standards.

We propose in a later section of this rule that using HL7 Version 3 for recording sex would be required under the ''Common Clinical Data Set'' definition for certification to the 2015 Edition. Please see section III.B.3 ''Common Clinical Data Set'' of this preamble for further discussion of this associated proposal.

Race and Ethnicity

We propose that, for certification (and testing) to this criterion, a Health IT Module must be capable of recording each one of a patient's races and ethnicities in accordance with, at a minimum, the ''Race & Ethnicity—CDC'' code system in the PHIN Vocabulary Access and Distribution System (VADS), Release 3.3.9.[21] We also propose that a Health IT Module must be able to aggregate each one of a patient's races and ethnicities to the categories in the OMB standard for race and ethnicity, which we previously adopted for the 2011 Edition and 2014 Edition ''demographics'' certification criteria.

As discussed in the 2014 Edition final rule (77 FR 54208), the OMB standard for the classification of data on race and ethnicity requires that the option for selecting one or more racial designations be provided. The standard also permits the use of more than the minimum standard categories for race and ethnicity, but requires that the data can be ''rolled up'' or mapped to the minimum standard categories as well as aggregated. The ''Race & Ethnicity—CDC'' code system in PHIN VADS (at a minimum, Release 3.3.9) permits a much more granular structured recording of a patient's race and ethnicity with its inclusion of over 900 concepts for race and ethnicity. The recording and exchange of patient race and ethnicity at such a granular level can facilitate the accurate identification and analysis of health disparities based on race and ethnicity. Further, the ''Race & Ethnicity—CDC'' code system has a hierarchy that rolls up to the OMB minimum categories for race and ethnicity and, thus, supports aggregation and reporting using the OMB standard. Accordingly, we propose the adoption and inclusion of both these standards in this certification criterion as described.

For the purposes of testing and certification to this ''demographics'' criterion, we would test that a Health IT Module can record each one of a patient's races and ethnicities using any of the 900 plus concepts in the ''Race & Ethnicity—CDC'' code system. We would not, however, expect the user interface to include a drop-down menu of all 900 plus ''Race & Ethnicity—CDC'' code system concepts for race and ethnicity, as we believe doing so could have negative workflow effects. Rather, we expect that health IT developers and health care providers would work together to establish the appropriate implementation given the care setting.

We refer readers to section III.A.2.d (''Minimum Standards'' Code Sets) for further discussion of our proposal to adopt ''Race & Ethnicity—CDC'' code system in PHIN VADS as a minimum standards code set and Release 3.3.9, or potentially a newer version if released before a subsequent final rule, as the baseline for certification to the 2015 Edition.

We propose in a later section of this proposed rule that the ''Race & Ethnicity—CDC'' code system in PHIN VADS (at a minimum, Release 3.3.9) and the OMB standard would become the race and ethnicity standards under the ''Common Clinical Data Set'' definition for certification to the 2015

[21] *https://phinvads.cdc.gov/vads/ViewCodeSystem.action?id=2.16.840.1.113883.6.238#.*

Edition. Please see section III.B.3 ''Common Clinical Data Set'' of this preamble for further discussion of this associated proposal.

Preferred Language

Based on specific HITSC recommendations from 2011, we adopted ISO 639–2 constrained by ISO 639–1 for recording preferred language in the 2014 Edition ''demographics'' certification criterion (77 FR 54208).[22] More specifically, this means that technology is required to be capable of using the alpha-3 codes of ISO 639–2 to represent the corresponding alpha-2 code in ISO–639–1. To provide further clarity, we issued FAQ 27 [23] in which we stated that where both a bibliographic code and terminology code are present for a required ISO 639–2 language, technology is expected to be capable of representing the language in accordance with the (T) terminology codes (ISO 639–2/T) for the purposes of certification. After we issued FAQ 27, we issued FAQ 43 [24] in which we acknowledge that our constrained approach to the use of ISO 639–2 unintentionally excluded multiple languages that are currently in use, such as sign language and Hmong. Additionally, ISO 639–2 is meant to support written languages, which may not be the language with which patients instinctively respond when asked for their preferred language.

To improve the situation described above, we propose to adopt the Internet Engineering Task Force (IETF) Request for Comments (RFC) 5646 [25] standard for preferred language. RFC 5646 entitled ''Tags for Identifying Languages, September 2009'' is the coding system that is commonly used to encode languages on the web and is the most current RFC for this purpose and listed as a ''best current practice.'' [26] The first part of the code relies on the shortest ISO–639 code for the language. That means a 2-character code if the language is specified in ISO 639–1 or a 3-character code from ISO 639–2 or –3, if the language is only listed in one of those two ISO standards. We are also aware that RFC 5646 supports dialects.

After consideration of comments we received on the Voluntary Edition proposed rule (79 FR 54450) and further research, we believe that RFC 5646 is the most appropriate standard to support preferred language interoperability. It is our understanding that this standard is compatible with the C–CDA Release 2.0 and that other preferred language standards in use today can be efficiently mapped to it, such as ISO 639–1, 639–2, and 639–3. Therefore, for the purposes of testing and certification to this ''demographics'' criterion, we would test that a Health IT Module can record a patient's preferred language using any of the codes in RFC 5646.

We emphasize that this requirement would apply to a Health IT Module presented for certification and not health care providers. In other words, a Health IT Module certified to this criterion would need to support the recording of preferred language in RFC 5646 and should in no way be interpreted or imply the way in which health care providers use the capability to record preferred language or the preferred language values they are presented with to select a patient's preferred language. For example, we would not expect the user interface to include a drop-down menu of all RFC 5646 codes for language, as we believe doing so could have negative workflow effects. Rather, we expect that health IT developers and health care providers would work together to establish the appropriate implementation given the care setting.

We propose in a later section of this proposed rule that RFC 5646 would also become the preferred language standard under the ''Common Clinical Data Set'' definition for certification to the 2015 Edition. Please see section III.B.3 (''Common Clinical Data Set'') of this preamble for further discussion of this associated proposal.

Preliminary Cause of Death and Date of Death

We propose to include in the 2015 Edition the capability to enable a user to electronically record, change, and access the ''date of death'' as a required capability that EHR technology designed for the inpatient setting must demonstrate. We previously included this capability as part of the 2011 Edition ''demographics'' certification criterion and inadvertently omitted it from the 2014 Edition. While we heard from commenters in response to the Voluntary Edition proposed rule that they were unaware of any developer removing this capability, we believe it is appropriate to specifically include this capability in the 2015 Edition criterion for testing and certification purposes and to align with the data required by the Meaningful Use criteria of the EHR Incentive Programs. To note, this functionality would be in addition to the inclusion in the 2015 Edition ''demographics'' certification criterion of the same capability to enable a user to electronically record, change, and access ''preliminary cause of death'' in case of mortality, as is included in the 2014 Edition ''demographics'' certification criterion.

- *Vital Signs, Body Mass Index (BMI), and Growth Charts*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(6) (Vital signs, body mass index, and growth charts)

We propose to adopt a 2015 Edition ''vital signs, BMI, and growth charts'' certification criterion that is revised in comparison to the 2014 Edition ''vital signs, BMI, and growth charts'' criterion (§ 170.314(a)(4)). Specifically, we propose to: 1) Expand the types of vital signs for recording; 2) require that each type of vital sign have a specific LOINC® code attributed to it; 3) that The Unified Code of Units of Measure, Revision 1.9, October 23, 2013 (''UCUM Version 1.9'') [27] be used to record vital sign measurements; and 4) that certain metadata accompany each vital sign, including date, time, and measuring- or authoring-type source.

Proposed Approach for Vital Signs

In the Voluntary Edition proposed rule (79 FR 10889–10890), we solicited comment on whether we should require health IT to record vital signs in standardized vocabularies. We solicited comments on whether we should require that vital signs be recorded in standardized vocabularies natively within the health IT system or only during transmission. We also solicited comment on whether we should require vital signs be recorded with specific metadata for contextual purposes.

Many commenters recommended that the industry should standardize how vital signs are represented and collected. To this end, we are aware that several stakeholder groups are working to define unique, unambiguous representations/definitions for clinical concepts along with structured metadata that together provide improved context for the system to interpret information, including vital signs. This approach can help increase data standardization at a granular level so that clinical elements and associated values/findings can be consistently represented and exchanged. For example, blood pressure is represented in current systems using a variety of formats, which creates

[22] *http://www.loc.gov/standards/iso639-2/php/code_list.php.*

[23] *http://www.healthit.gov/policy-researchers-implementers/27-question-10-12-027.*

[24] *http://www.healthit.gov/policy-researchers-implementers/43-question-11-13-043.*

[25] *http://www.rfc-editor.org/info/rfc5646.*

[26] *http://www.rfc-editor.org/info/rfc5646.*

[27] *http://unitsofmeasure.org/trac/.*

significant challenges to aggregate, compare, and exchange data across systems. This occurs despite the numeric nature of blood pressure, resulting in costly and time-consuming manual translation to integrate this data across systems.

Some commenters supported requiring standardized vocabularies for vital signs during data exchange rather than natively within the health IT system. While we agree that data should be exchanged in a standard way, we also believe that the granularity necessary to unambiguously represent this data should be implemented within health IT systems so that data is captured with the same level of specificity to enable consistent and reliable interpretation by other data users and receivers without requiring mapping. Thus, we propose that health IT demonstrate it is able to record vital signs data natively as specified below. Overall, these proposals reflect our interest in ensuring that the data a user enters into a health IT system is semantically and syntactically identical to the information coming out of the system and being exchanged. We believe this would increase the confidence that the data exchanged is what the provider intended.

The 2014 Edition ''vital signs'' certification criterion requires health IT to enable a user to electronically record, change, and access a patient's height/length, weight, and blood pressure. We propose to include BMI, heart rate, respiratory rate, temperature, oxygen saturation in arterial blood by pulse oximetry, and mean blood pressure as we understand that these vital signs are commonly captured or calculated (*i.e.,* BMI) in the routine course of clinical encounters across a wide variety of both inpatient and ambulatory settings. We also propose to further specify that health IT would need to be able to record diastolic and systolic blood pressure as separate vital signs rather than ''blood pressure'' (unspecified) as a single vital sign. We clarify that this list of vital signs is not intended to be comprehensive. Rather, these listed vital signs indicate our interest in a more specific approach to recording and exchanging vital signs data that could promote unambiguous interpretation. These vital sign concepts derive from the C–CDA standard and the Public Health Information Network Vocabulary Access and Distribution System value set for vital sign result types [28] (2.16.840.1.113883.3.88.12.80.62), which was developed by the Health IT Standards Panel.[29] Therefore, we believe the health care community has experience with collecting these vital sign concepts because they have been defined for some time as part of previous collaborative stakeholder work.

We propose to require that a Health IT Module be able to attribute a specific LOINC® code to each type of vital sign using the following identifiers:

- ''Systolic blood pressure'' with LOINC® code 8480–6;
- ''Diastolic blood pressure'' with LOINC® code 8462–4;
- ''Body height'' with LOINC® code 8302–2;
- ''Body weight measured'' with LOINC® code 3141–9;
- ''Heart rate'' with LOINC® code 8867–4;
- ''Respiratory rate'' with LOINC® code 9279–1;
- ''Body temperature'' with LOINC® code 8310–5;
- ''Oxygen saturation in arterial blood by pulse oximetry'' with LOINC® code 59408–5;
- ''Body mass index (BMI) [Ratio]'' with LOINC® code 39156–5; and
- ''Mean blood pressure'' with LOINC® code 8478–0.

We understand that the industry is commonly identifying these vital signs using LOINC® codes today.

We also propose to require that a Health IT Module enable a user to record these vital signs with at least the following metadata:

- date and time of vital sign measurement or end time of vital sign measurement with optional certification in accordance with the clock synchronization standard adopted at § 170.210(g); and
- the measuring- or authoring-type source of the vital sign measurement (such as the user who documented the vital sign or the medical device that was used to measure the vital sign).

In some cases, the provider documenting the vital sign may record the date and time of vital sign measurement manually and enter the data into a health IT system at a later time; therefore, it would not be necessary to use the clock synchronization standard. However, use of the clock synchronization standard may be useful for situations where the vital sign data comes from a device and should be synchronized with the health IT system.

For ''oxygen saturation in arterial blood by pulse oximetry,'' we propose that a Health IT Module enable a user to record ''inhaled oxygen concentration'' with LOINC® code 3150–0 as metadata associated with the vital sign. We understand that ''inhaled oxygen concentration'' is frequently provided to assist with interpretation of the ''oxygen saturation in arterial blood by pulse oximetry'' value.

For all units of measure associated with a vital sign value, we propose to require that health IT be able to record an applicable unit of measure in accordance with UCUM Version 1.9 (*e.g.,* the UCUM unit ''mm[Hg]'' for systolic blood pressure; *e.g.,* the UCUM unit ''[lb_av],'' ''g,'' ''kg,'' or ''[oz_av]'' for body weight). We note that LOINC provides a translation table [30] that enumerates the UCUM syntax for a subset of UCUM codes that are commonly used in health IT that may be a useful reference for stakeholders.

Proposed ''Optional'' Pediatric Vital Signs

We propose to offer optional certification for health IT to be able to electronically record, change, and access:

- Body mass index (BMI) [Percentile] per age and sex (with LOINC® code 59576–9) for youth 2–20 years of age; and
- Weight for length per age and sex (with LOINC® code to be established in a newer version of LOINC® prior to the publication of a subsequent final rule) and/or Head occipital-frontal circumference by tape measure (with LOINC® code 8287–5) for infants less than 3 years of age.

We propose to require that a Health IT Module enable each optional vital sign to be recorded with an applicable unit of measure in accordance with UCUM Version 1.9. CDC recommends the collection of these anthropomorphic indices for youth 2–20 years of age and infants less than 3 years of age, respectively, as part of best care practices.[31]

A Health IT Module certified to the ''BMI percentile per age and sex,'' ''weight for length per age and sex,'' or ''head occipital-frontal circumference by tape measure'' vital signs would also need to record metadata for the date and time or end time of vital sign

[28] *https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.113883.3.88.12.80.62.*

[29] The Health IT Standards Panel was established in 2005 as a strategic public-private partnership in contract with the U.S. Department of Health and Human Services to achieve a widely accepted and useful set of standards to enable and support widespread interoperability among healthcare software applications. The Health IT Standards Panel's contract with HHS concluded on April 30, 2010. *http://www.hitsp.org/.*

[30] *https://loinc.org/downloads/usage/units.*

[31] *http://www.cdc.gov/growthcharts/clinical_charts.htm#Set1* and *http://www.cdc.gov/growthcharts/clinical_charts.htm#Set2.*

measurement, the measuring- or authoring-type source of the vital sign measurement, the patient's date of birth, and the patient's sex in accordance with the standard we propose to adopt at § 170.207(n)(1). We believe offering optional certification to these three vital signs can provide value in settings where pediatric and adolescent patients are provided care.

Request for Comments on Vital Signs Proposal

We intend that the LOINC® codes proposed for attribution to the vital signs in the list above are neutral to, and therefore can encompass, any clinically reasonable method of measurement that is commonly used in obtaining vital signs in the course of clinical encounters in a wide variety of contexts, including but not limited to, primary-care office/clinic visits, emergency department visits, and routine inpatient admissions processes. For example, this would mean the system would attribute ''body height'' to LOINC® code 8302–2 for the measurement of how tall or long the patient is. This measurement is collected as part of routine vital signs observation regardless of whether this clinical observation was made by measuring a standing or supine adult/child, or a supine infant, or by estimating through clinically reasonable methods the height/length of an adult or child who cannot be measured in a standing or fully supine position.

Likewise, we propose to attribute a specific LOINC® code for body temperature regardless of whether the temperature was measured by a liquid-filled, digital/electronic, or infrared (non-contact) thermometer. The choice of UCUM unit code will indicate whether the measurement was taken in English or metric units. The metadata describing the source of the measurement would provide the context of the device that was used to perform the measurement. We reiterate that the intent behind this ''vital signs'' proposal is to ensure that the data a user enters into a health IT system is semantically and syntactically identical to the information coming out of the system and being exchanged, allowing other users to unambiguously and consistently interpret the information. We anticipate that stakeholders may want to expand the list of metadata beyond the date, time, and source of vital sign measurement. We welcome comment on additional vital sign metadata that we should consider for inclusion and the best available standards for representing the metadata (*e.g.,* LOINC® or a similar standard).

Health IT users may currently capture vital signs in more granular LOINC® codes that specify the method of measurement. We therefore solicit comment on the feasibility and implementation considerations for our proposals that rely on less granular LOINC® codes for attribution to vital sign measurements and the inclusion of accompanying metadata. Additionally, we solicit comment on the following issues:

- Support for or against the proposal to require attribution of vital sign values using specific LOINC® codes and associated metadata;
- whether our proposal will accomplish the stated goal of ensuring that the vital signs data a user enters into a health IT system is semantically and syntactically identical to the information coming out of the system and being exchanged;
- whether the LOINC® codes proposed above are the correct ones for representing the vital sign concepts broadly, including any method of measurement; and
- standards for recording the source of the vital sign measurement.

We also solicit comment on whether we should require a Health IT Module to be able to record metadata specific to particular vital signs results/findings. This could provide additional contextual information (*e.g.,* position for diastolic and systolic blood pressure, whether the patient is breathing supplemental oxygen, the site of the temperature such as oral or rectal, pregnancy status for BMI, and whether the vital sign was measured or self-reported). Because the LOINC® code associated with some vital sign concepts we are proposing may include whether the vital sign was measured or self-reported (*e.g.,* body weight measured), we also request comment on which specific vital signs should include metadata on whether it was measured or self-reported. If we were to require a Health IT Module to be able to record metadata specific to particular vital signs, we solicit comment on what additional metadata should be required for certification and what standards (*e.g.,* LOINC® or a similar standard) we should consider for representing that data.

We note, with respect to arterial oxygen saturation, that we are proposing here the type of measurement that we understand to be commonly performed as part of vital signs observation across a wide variety of clinical settings. We are aware that in some clinical circumstances oxygen saturation in arterial blood by pulse oximetry is not a sufficiently precise measurement to support sound clinical decisions. We therefore invite comment as to whether we should consider defining the arterial blood oxygen saturation vital sign in a more method-agnostic way, and whether we should also require capture and exchange of more robust metadata to ensure technology could reliably identify to clinicians seeking to use the value whether it was measured by pulse oximetry or a more precise but more invasive and, in most clinical contexts, less commonly performed arterial blood gas (ABG) test.

We propose in a later section of this proposed rule that vital signs be represented in same manner for the ''Common Clinical Data Set'' definition as it applies to the certification of health IT to the 2015 Edition. Note that the optional portions of the proposed vital signs criterion would not be required for the ''Common Clinical Data Set'' (*i.e.,* BMI percentile per age and sex for youth, weight for length for infants, head occipital-frontal circumference by tape measure, calculating BMI, and plotting and displaying growth charts.) Please see section III.B.3 (''Common Clinical Data Set'') of this preamble for further discussion of this associated proposal.

- *Problem List*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(7) (Problem list)

We propose to adopt a 2015 Edition ''problem list'' certification criterion that is revised in one way as compared to the 2014 Edition ''problem list'' certification criterion (§ 170.314(a)(5)). We propose to include the September 2014 Release of the U.S. Edition of SNOMED CT® in the 2015 Edition ''problem list'' certification criterion as the baseline version permitted for certification to this criterion. The 2014 Edition ''problem list'' criterion included the July 2012 Release of SNOMED CT® (International Release and the U.S. Extension) as the baseline version permitted for certification. We also refer readers to section III.A.2.d (''Minimum Standards'' Code Sets) for further discussion of our adoption of SNOMED CT® as a minimum standards code set and our proposal to adopt the September 2014 Release (U.S. Edition), or potentially a newer version if released before a subsequent final rule, as the baseline for certification to the 2015 Edition.

- *Medication List*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(8) (Medication list)

We propose to adopt a 2015 Edition ''medication list'' certification criterion that is unchanged as compared to the 2014 Edition ''medication list'' certification criterion (§ 170.314(a)(6)). To note, this proposed criterion does not reference any standards or implementation specifications.

- *Medication Allergy List*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(9) (Medication allergy list)

We propose to adopt a 2015 Edition ''medication allergy list'' certification criterion that is unchanged as compared to the 2014 Edition ''medication allergy list'' certification criterion (§ 170.314(a)(7)).

We received comments in response to the Voluntary Edition proposed rule suggesting that a ''medication allergy list'' criterion should include also other types of allergies and intolerances, such as food and environmental allergies (79 FR 54451–52). We are aware of a number of vocabularies and code sets that could support food and environmental allergies as well as medications, but believe that the industry is working on identifying ways that multiple vocabularies and code sets can be used together in an interoperable way to support coding of allergies. Therefore, at this time, there is no ready solution for using multiple vocabularies to code allergies that could be adopted for the purposes of certification.

- *Clinical Decision Support*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(10) (Clinical decision support)

Health IT is key component of advanced health models and delivery system reform. CDS is a primary means of supporting the implementation of best evidence and new knowledge at the point of care and in real time (see our definition of ''CDS intervention'' discussed at 77 FR 13847). When effective decision support is presented in a useful manner, it enhances usability and helps providers and patients avoid medical errors. Therefore, we believe that clinical decision support is a crucial feature of certified health IT.

We propose to adopt a 2015 Edition ''clinical decision support'' certification criterion that is revised in comparison to the 2014 Edition ''CDS'' criterion (§ 170.314(a)(8)). We propose to adopt and include an updated ''Infobutton'' [32] standard and two updated associated IGs. We propose to require certification only to the Infobutton standard (and an associated IG) for identifying diagnostic or therapeutic reference information. We propose to require that a Health IT Module presented for certification to this criterion be able to record users' actions in response to CDS interventions. Last, we have revised the regulation text in comparison to the 2014 Edition CDS criterion to provide more clarity for certification to this proposed criterion as well as guidance for certification to the 2014 Edition CDS criterion.

Infobutton Standard and IGs

We propose to adopt and include the updated Infobutton standard (Release 2, June 2014) [33] in the proposed 2015 Edition CDS criterion. Infobutton provides a standard mechanism for health IT systems to request context-specific clinical or health knowledge from online resources. We propose to adopt and include the HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1, August 2013 (''SOA Release 1 IG'') [34] in the CDS criterion. The SOA Release 1 IG includes additional conformance criteria, redesigns extensions, revises possible values, and includes support for an additional format for representing knowledge responses. We also propose to adopt and include in the proposed 2015 Edition CDS criterion the updated Infobutton URL-based IG (HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4, June 2014) (''URL-based Release 4 IG'').[35] The IG provides a standard mechanism for health IT to submit knowledge requests to knowledge resources over the HTTP protocol using a standard URL format.

We propose to adopt the updated Infobutton standard with the SOA Release 1 IG at § 170.204(b)(3). We propose to adopt the updated Infobutton standard with the URL-based Release 4 IG at § 170.204(b)(4). We clarify that as proposed, a Health IT Module presented for certification would need to demonstrate the ability to electronically identify for a user diagnostic and therapeutic reference information in accordance with § 170.204(b)(3) *or* (b)(4) (*i.e.,* Infobutton and the SOA Release 1 IG *or* Infobutton and the URL-based Release 4 IG).

For certification to the 2014 Edition CDS criterion, we permit a health IT to be certified if it can electronically identify for a user diagnostic and therapeutic reference information using the Infobutton standard *or* another method (§ 170.314(a)(8)(ii)). For the 2015 Edition CDS criterion, we propose to require that a Health IT Module must be able to identify linked referential CDS information using the Infobutton standard *only,* as we believe this is the best consensus-based standard available to support this use case. We have taken this approach because certification focuses on the capabilities health IT can demonstrate (where applicable, according to specific standards) and not on how it is subsequently used. Thus, with this focus we believe we can refrain from continuing a regulatory requirement (*i.e.,* requiring ''another method'' for certification) from the 2014 Edition to the 2015 Edition.

For the proposed 2015 Edition ''patient-specific education resources'' certification criterion discussed later in this section of the preamble, we propose, for the purposes of certification, to require that a Health IT Module be able to request patient-specific education resources based on a patient's preferred language. We believe this capability would assist providers in addressing and mitigating certain health disparities. We solicit comment on whether we should require this functionality as part of the CDS certification criterion for reference materials identified using the Infobutton standards, including examples of use cases for which this functionality would be appropriate. We note that if should require a Health IT Module to be able to request patient-specific education resources based on a patient's preferred language as part of the CDS criterion, the availability of resources in a patient's preferred language depends on the material supported by the content provider. Therefore, to clarify, testing and certification would focus on the ability of the Health IT Module to make the request using a preferred language and Infobutton.

CDS Intervention Response Documentation

We solicited comment in the Voluntary Edition proposed rule on whether a Health IT Module should be able to record users' responses to the DD/DAI checks that are performed,

[32] Infobutton'' is typically the shorthand name used to refer to the formal standard's name: HL7 Version 3 Standard: Context-Aware Retrieval Application (Infobutton)

[33] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=208.*

[34] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=283.*

[35] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=22.*

including if and when the user viewed, accepted, declined, ignored, overrode, or otherwise commented on the product of a DD/DAI check. We also received comments recommending we broaden our consideration to include functionality for recording user responses for all CDS interventions. We believe that this functionality could be valuable for all CDS interventions, not solely DD/DAI checks, because it could assist with enhancing CDS intervention design and implementation, quality improvement, and patient safety.

As such, we propose that the CDS criterion include functionality at § 170.315(a)(10)(vi) that would require a Health IT Module to be able to record at least one action taken and by whom when a CDS intervention is provided to a user (*e.g.,* whether the user viewed, accepted, declined, ignored, overrode, provided a rationale or explanation for the action taken, took some other type of action not listed here, or otherwise commented on the CDS intervention). We also propose that a Health IT Module be able to generate either a human readable display or human readable report of the responses and actions taken and by whom when a CDS intervention is provided.

We note that we do not believe that a Health IT Module's ability to record user responses should increase provider burden in order to just meet this criterion. For example, we would not encourage implementations that would unnecessarily (*e.g.,* for a non-clinical or safety-related reason) interrupt a provider's workflow and require the provider to document the reason just to meet this criterion. Rather, we encourage health IT developers to leverage current best practices for presenting, documenting, and facilitating the safest and most appropriate clinical options in response to CDS interventions.

Clarifying ''Automatically'' and ''Triggered'' Regulatory Text

CDS can include a broad range of decision support interventions and are not solely limited to alerts. Our 2014 Edition ''CDS'' criterion uses the terms ''automatically'' and ''triggered'' when referencing interventions. The use of ''trigger'' and ''automatic'' can be associated with CDS rules or alerts, but may not encompass all kinds of CDS interventions. For example, CDS could be seamlessly presented in the user interface (*e.g.,* a dashboard display) or selected by the user within the workflow (*e.g.,* Infobutton or documentation flowsheets). The use of ''automatically'' and ''trigger'' as related to CDS interventions in the 2014 Edition ''CDS'' caused confusion as to what types of CDS interventions were permitted. To clarify, our intent is to encompass all types of CDS interventions without being prescriptive on how the interventions are deployed (*e.g.,* automatic, triggered, selected, seamless, or queried). As such, we are not using the terms ''automatically'' and ''trigger'' as related to CDS interventions in the regulatory text for this 2015 Edition certification criterion. However, we do not propose to change the regulatory text language in the 2014 Edition ''CDS'' certification criterion as current testing and certification under the ONC Health IT Certification Program permits the other types of interventions we have described above.

2014 Edition ''Clinical Decision Support'' Certification Criterion—Corrections

We propose to revise the cross-reference in § 170.314(a)(8)(iii)(B)(*2*) (CDS configuration) to more specifically cross-reference the 2014 ToC criterion (§ 170.314(b)(1)(iii)(B)). This more specific cross reference aligns with the our other proposed revision to this criterion, which is to add a cross-reference to § 170.314(b)(9)(ii)(D). We inadvertently omitted the cross-reference to § 170.314(b)(9)(ii)(D) in the 2014 Edition Release 2 final rule. These revised cross-references would more clearly indicate that health IT certified to the 2014 Edition CDS criterion would need to enable CDS interventions when a patient's medications, medication allergies, and problems are incorporated from a transition of care/care referral summary.

• *Drug Formulary and Preferred Drug List Checks*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(11) (Drug-formulary and preferred drug list checks)

We propose to adopt a 2015 Edition ''drug formulary checks and preferred drug list'' certification criterion that is revised in comparison to the 2014 Edition ''drug formulary checks'' certification criterion (§ 170.314(a)(10)). We propose a criterion that is split based on drug formularies and preferred drug lists. For drug formularies, we propose that a Health IT Module must (1) automatically check whether a drug formulary exists for a given patient and medication and (2) receive and incorporate a formulary and benefit file according to the NCPDP Formulary and Benefit Standard v3.0 (''v3.0''). We propose to adopt v3.0 at § 170.205(n)(1), but also solicit comment on more recent versions of the NCPDP Formulary and Benefit Standard. For preferred drug lists, we propose that a Health IT Module must automatically check whether a preferred drug list exists for a given patient and medication. This situation applies where the health IT system does not use external drug formularies, such as in a hospital health IT system. We also propose, for both drug formularies and preferred drug lists, that a Health IT Module be capable of indicating the last update of a drug formulary or preferred drug list as part of certification to this criterion. We believe that health IT should indicate the last update of the drug formulary or preferred drug list so the provider knows how recently the information was last updated. We also solicit comment on the best standard for individual-level, real-time formulary benefit checking to address the patient co-pay use case, and whether we should offer health IT certification to the standard for this use case.

As described in more detail in the Voluntary Edition proposed rule (79 FR 10892), CMS finalized a proposal to recognize NCPDP Formulary and Benefit Standard v3.0 as a backwards compatible version of NCPDP Formulary and Benefit Standard 1.0 for the period of July 1, 2014 through February 28, 2015, and to retire version 1.0 and adopt version 3.0 as the official Part D e-Prescribing standard on March 1, 2015 (78 FR 74787–74789). In response to the Voluntary Edition proposed rule, we received comments supporting adoption of the NCPDP Formulary and Benefit Standard v3.0 (''v3.0'') for this edition of certification criteria. Those commenters in support of adopting v3.0 noted the potential to reduce file sizes, which is beneficial when checking thousands of drug formularies on a daily basis. We agree with those commenters that v3.0 is the best available option for standardizing the implementation of drug-formulary checks in health IT and for its potential to reduce file sizes. As noted above, the adoption of v3.0 would also align with CMS' adoption of version 3.0 as the official Part D e-Prescribing standard beginning March 1, 2015.

We are aware that more recent versions of the NCPDP Formulary and Benefit Standard. Versions 4.0 (''v4.0'') (January 2013), 4.1 (''v4.1'') (October 2013), and 42 (October 2014) (''v42'') [36] have been published and are available for industry use. At the time of this

[36] Please note a change to the naming convention to Version 42 and Version 43, as NCPDP accepted a change request to remove the period in version numbering.

proposed rule, we understand that the NCPDP is currently developing and balloting Version 43 (''v43''). Version 4.0 has minor changes compared to v3.0, including removal of values from an unused diagnosis code, typographical corrections, and a change to the standard length of the name field. Version 4.1 removes files to support electronic prior authorization (ePA) transactions since these have been added to the NCPDP SCRIPT Standard Implementation Guide v2013011 (January 2013) and later versions, makes typographical corrections, adds a new coverage type for ePA routing, and adds an RxNorm qualifier to some data elements. V42 includes changes to reduce the file size. Stakeholder feedback has indicated that v4.0, v4.1, and v42 are backwards compatible with v3.0 for the elements that are the same as compared to v3.0.

We received mixed comments in response to the Voluntary Edition proposed rule on whether it is more appropriate to adopt v4.0 instead of v3.0 (79 FR 54454). Some commenters were concerned about known problems with v3.0 and indicated v4.0 could fix these known problems. Conversely, other commenters stated that v4.0 was too unstable and new for an edition of certification criteria that was anticipated to be adopted and in use in 2014. With these comments in mind, we solicit comment on whether we should adopt v4.0, v4.1, or v42 of the NCPDP Drug and Formulary Benefit Standard instead of v.3.0 for the proposed 2015 Edition ''drug formulary checks and preferred drug list'' criterion and what unintended impacts this could have on the industry given the Part D requirements.

We believe there is value in certifying that health IT is able to receive and incorporate a formulary and benefit file in accordance with the NCPDP Formulary and Benefit Standard v3.0. Systems would be able to incorporate more updated or complete formulary and benefit files to inform providers as they make determinations about which medications to prescribe their patients. We seek to understand the potential system burden in incorporating formulary and benefit files and, therefore, seek comment on this issue.

In the Voluntary Edition proposed rule, we noted that the NCPDP Formulary and Benefit Standard v3.0 did not address individual-level, real-time formulary benefit checking. Comments in response to the Voluntary Edition proposed rule noted that the ASC X12 270/271 Health Care Eligibility Benefit Inquiry and Response standard could perform individual-level, real-time formulary benefit checking in addition to the NCPDP Telecommunication Standard. Commenters also noted that e-prescribing networks could provide this service to customers within proprietary networks. We are aware of a recently established NCPDP task group that is defining potential use cases and business requirements for real-time benefit checking.

We continue to believe in the value of providers and patients knowing what the patient's cost sharing responsibilities are at the point of care for a given medication to inform discussions about a patient's care. Therefore, for this use case, we ask commenters to identify the best standard(s) for individual-level, real-time (at the point of care) formulary benefit checking and describe how the standard addresses this use case. We also solicit comment on whether we should offer certification for this use case using the appropriate standard for individual-level, real-time formulary benefit checking and whether it should be part of the 2015 Edition ''drug formulary and preferred drug list checks'' certification criterion or a standalone certification criterion.

- *Smoking Status*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(12) (Smoking status)

We propose to adopt a 2015 Edition ''smoking status'' certification criterion that is revised in comparison to the 2014 Edition ''smoking status'' criterion (§ 170.314(a)(11)). We propose that a Health IT Module must be able to record, change, and access smoking status in *any* of the available codes for smoking status in, at a minimum, the September 2014 Release of the U.S. Edition of SNOMED CT®.[37] We have taken this more flexible approach because there is no longer a proposed meaningful use objective and measure associated with this requirement and, thus, no specific requirement for certain codes to be used toward numerator calculation.

We note, however, that the 8 smoking status SNOMED CT® codes identified in § 170.207(h)[38] remain the same codes as identified for the 2014 Edition. They are also the value set included in the Common Clinical Data Set for the 2015 Edition and the only codes permitted for representing smoking status for electronic transmission in a summary care record for the purposes of certification. Therefore, a Health IT Module certified to certification criteria that reference the Common Clinical Data Set (*i.e.,* the ToC, data portability, VDT, Consolidated CDA creation performance, and application access to the Common Clinical Data Set certification criteria) would need to be able to code smoking status in only the 8 smoking status codes, which may mean mapping other smoking status codes to the 8 codes.

We also note that we would not expect the user interface to include a drop-down menu of all available SNOMED CT® smoking status codes, as we believe doing so could have negative workflow effects. Rather, we expect that health IT developers and health care providers would work together to establish the appropriate implementation given the care setting.

We propose to include the 2015 Edition ''smoking status'' certification criterion in the 2015 Edition Base EHR definition. Please see section III.B.1 of this preamble for further discussion of this associated proposal.

- *Image Results*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(13) (Image results)

We propose to adopt a 2015 Edition ''image results'' certification criterion that is unchanged in comparison to the 2014 Edition ''image results'' criterion (§ 170.314(a)(12)).

- *Family Health History*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(14) (Family health history)
2015 Edition Health IT Certification Criterion
§ 170.315(a)(15) (Family health history—pedigree)

We propose to adopt two 2015 Edition ''family health history'' (FHH) certification criteria. Both proposed criteria are revised in comparison to the 2014 Edition FHH certification criterion (§ 170.314(a)(13)). The proposed 2015 Edition FHH certification criterion at § 170.315(a)(14) would require

[37] We refer readers to section III.A.2.d (''Minimum Standards'' Code Sets) for further discussion of our adoption of SNOMED CT® as a minimum standards code set and our proposal to adopt the September 2014 Release (U.S. Edition), or potentially a newer version if released before a subsequent final rule, as the baseline for certification to the 2015 Edition.

[38] These 8 codes are: Current every day smoker, 449868002; current some day smoker, 428041000124106; former smoker, 8517006; never smoker, 266919005; smoker—current status unknown, 77176002; unknown if ever smoked, 266927001; heavy tobacco smoker, 428071000124103; and light tobacco smoker, 428061000124105.

technology to enable a user to record, change, and access a patient's FHH electronically according to, at a minimum, the concepts or expressions for familial conditions included in the September 2014 Release of the U.S. Edition of SNOMED CT®. We refer readers to section III.A.2.d (''Minimum Standards'' Code Sets) for further discussion of our adoption of SNOMED CT® as a minimum standards code set and our proposal to adopt the September 2014 Release (U.S. Edition), or potentially a newer version if released before a subsequent final rule, as the baseline for certification to the 2015 Edition.

The proposed 2015 Edition FHH—pedigree certification criterion at § 170.315(a)(15) would require technology to enable a user to create and incorporate a patient's FHH according to HL7 Pedigree standard and the HL7 Pedigree IG, HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability, Release 1.[39] We believe that this approach gives the most flexibility to health IT developers and providers to develop, adopt, and implement technology that supports their clinical documentation needs, while still enabling interoperability. For example, some providers may only need technology that supports FHH coding in SNOMED CT®. Other providers may also want technology that supports genomic coding, which HL7 Pedigree can support. The adoption of two separate criteria can more effectively support different use cases and clearly identify the capabilities to which health IT has been certified.

As part of the 2014 Edition final rule, we incorrectly assigned the HL7 Pedigree standard to § 170.207 where we adopt ''vocabulary'' standards. Accordingly, for the 2015 Edition, we have placed the HL7 Pedigree standard and its IG in § 170.205(m)(1) to more accurately place it in the ''content'' exchange standards section of the CFR.

• *Patient List Creation*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(16) (Patient list creation)

We propose to adopt a 2015 Edition ''patient list creation'' certification criterion that is unchanged in comparison to the 2014 Edition ''patient list creation'' criterion (§ 170.314(a)(14)). We propose to incorporate our guidance provided in FAQ 39[40] into the 2015 Edition ''patient list creation'' criterion. Specifically, the text of the 2015 Edition ''patient list creation'' certification criterion provides that a Health IT Module must demonstrate its capability to use at least one of the more specific data categories included in the ''demographics'' certification criterion (§ 170.315(a)(5)) (*e.g.,* sex or date of birth).

• *Patient-Specific Education Resources*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(17) (Patient-specific education resources)

We propose to adopt a 2015 Edition ''patient-specific education resources'' certification criterion that is revised in comparison to the 2014 Edition ''patient-specific education resources'' certification criterion (§ 170.314(a)(15)). We propose that certification would only focus on the use of Infobutton for this certification criterion instead of Infobutton *and* any means other than Infobutton as required by the 2014 Edition criterion. We have reviewed the regulatory burden posed by the 2014 Edition criterion and determined that there is diminished value in continuing to frame the 2015 Edition certification criterion in this way. We continue to believe, however, that the Infobutton capability is important to be available to providers to have and use to identify patient-specific education resources.

We propose to adopt the updated Infobutton standard (Release 2 and the associated updated IGs (SOA-based IG and URL-based IG)). These are discussed in more detail under the ''CDS'' certification criterion earlier in this section of the preamble. We also note that we no longer include a requirement that health IT be capable of electronically identifying patient-specific education resources based on ''laboratory values/results.'' We understand from stakeholder feedback on the 2014 Edition version of this criterion and our own research that the Infobutton standard cannot fully support this level of data specificity. For example, Infobutton could likely provide something useful for results that are a concept like ''E.coli,'' but not necessarily a numerical laboratory result.

We also propose that a Health IT Module be able to request patient-specific education resources based on a patient's preferred language as this would assist providers in addressing and mitigating certain health disparities. More specifically, we propose that a Health IT Module must be able to *request* that patient-specific education resources be identified (using Infobutton) in accordance with RFC 5646. We are aware, however, that Infobutton only supports a value set of ISO 639–1 for preferred language and, therefore, testing and certification of preferred language for this certification criterion would not go beyond the value set of ISO 639–1. To note, we also understand that the language of patient education resources returned through Infobutton is dependent on what the source can support. Thus, we reiterate that testing and certification would focus on the ability of the Health IT Module to make the request using a preferred language and Infobutton.

• *Electronic Medication Administration Record*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(18) (Electronic medication administration record)

We propose to adopt a 2015 Edition electronic medication administration record (eMAR) certification criterion that is unchanged in comparison to the 2014 Edition ''eMAR'' criterion (§ 170.314(a)(16)).

• *Patient Health Information Capture*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(19) (Patient health information capture)

We propose to adopt a new 2015 Edition ''patient health information capture'' certification criterion that would ''replace'' the 2014 Edition ''advance directives'' certification criterion (§ 170.314(a)(17)) for the purposes of certification to the 2015 Edition. The HITPC recommended, as part of their EHR Incentive Programs Stage 3 recommendations, that we adopt a certification criterion for ''advance directives'' that would require a Health IT Module to be capable of storing an advance directive and/or including more information about the advance directive, such as a link to the advance directive or instructions regarding where to find the advance directive or more information about it.[41] We agree with this recommendation in that more functionality should be demonstrated for certification as it relates to advance directives. Further, we believe that the functionality described by the HITPC can be more broadly applicable and, thus, have named this certification criterion to reflect functionality that can be applied to various patient health information documents. For example,

[39] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=301.*

[40] *http://www.healthit.gov/policy-researchers-implementers/39-question-04-13–039.*

[41] *http://www.healthit.gov/facas/sites/faca/files/HITPC_MUWG_Stage3_Recs_2014-04-01.pdf.*

we believe such capabilities could be applicable to birth plans as well as advance directives.

For certification to this criterion, we propose that a Health IT Module would need to properly identify health information documents for users (*e.g.,* label health information documents as advance directives and birth plans). A Health IT Module would also need to be able to demonstrate that it could enable a user to record (capture and store) and access (ability to examine or review) health information documents.

We further propose that a Health IT Module would need to be able to reference health information documents, which means providing narrative information on where to locate a specific health information document. A Health IT Module would also need to demonstrate that it can link to patient health information documents. ''Linking'' would require a Health IT Module to demonstrate it could link to an internet site storing a health information document. While an intranet link to a health information document might suffice for provider use, a Health IT Module would still need to demonstrate the ability to link to an external site via the internet for the purposes of certification.

We also propose that a Health IT Module would be required to demonstrate that it could enable a user to record and access information directly and electronically shared by a patient. This could come from multiple sources, including patient information provided directly from a mobile device. To note, we have not proposed any specific standards for this criterion related to receiving and accepting information directly and electronically shared by a patient.

We clarify that these capabilities may not be applicable to every patient health information document, but a Health IT Module would need to be able to perform all of these capabilities electronically for certification to this criterion.

- *Implantable Device List*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(20) (Implantable device list)

We propose to adopt a new 2015 Edition certification criterion focused on the ability of a Health IT Module to record, change, and access a list of unique device identifiers (UDIs) [42] corresponding to a patient's implantable devices (''implantable device list''), parse certain data from a UDI, retrieve the ''Device Description'' attribute associated with a UDI in the Global Unique Device Identification Database (GUDID), and make accessible to a user both the parsed and retrieved data. The proposed criterion represents a first step towards enabling health IT to facilitate the widespread availability and use of unique device identifiers to prevent device-related adverse events, enhance clinical decision-making related to devices, improve the ability of clinicians to respond to device recalls and device-related safety information, and achieve other important benefits, consistent with the fundamental aims of the HITECH Act [43] and the HHS Health IT Patient Safety Action and Surveillance Plan.[44]

FDA issued the Unique Device Identification System final rule on September 24, 2013.[45] The rule implements a statutory directive to establish a ''unique device identification system'' for medical devices that will enable adequate identification of devices through distribution and use.[46] It accomplishes this objective by requiring device labelers (usually the device manufacturer) to include a UDI on the label and packages of most medical devices subject to FDA jurisdiction. In addition, for each device with a UDI, the labeler must submit a standard set of identifying data elements to the FDA-administered GUDID, which will be publicly accessible.[47] Full implementation of the UDI system for devices that are implantable, life-saving, and life-sustaining is required by September 2015.[48]

We first proposed to adopt a certification criterion for implantable devices in the Voluntary Edition proposed rule (79 FR 10894). We received a large volume of comments on our proposal, many of which supported the adoption of a UDI-related certification criterion focused on implantable device list functionality. Some supporters of our proposal suggested that we wait to adopt it in our next rulemaking cycle in order to allow relevant standards and use cases to mature. Other commenters, mostly health IT developers, suggested that the proposed criterion would be applicable only to health IT systems designed for surgical or specific inpatient settings in which devices are implanted, and therefore suggested that we reduce the scope of the criterion to those settings.[49] For the reasons stated in the 2014 Edition Release 2 final rule,[50] we finalized only a small subset of the criteria we had originally proposed in the Voluntary Edition proposed rule. These criteria focused on adding flexibility and making improvements to the 2014 Edition. Consistent with this reduced scope, we did not finalize an implantable device list criterion at that time, stating instead our intention to propose such a criterion in our next rulemaking that would provide additional detail and clarity, as well as respond to concerns raised by commenters.

We continue to believe that incorporating UDIs in health IT is important and necessary to realize the significant promise of UDIs and FDA's

[42] A UDI is a unique numeric or alphanumeric code that consists of two parts: (1) a device identifier (DI), a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and (2) a production identifier (PI), a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device: the lot or batch number within which a device was manufactured; the serial number of a specific device; the expiration date of a specific device; the date a specific device was manufactured; the distinct identification code required by 21 CFR 1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device. *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/.*

[43] Specifically, the certification criterion supports the National Coordinator's responsibility under the HITECH Act to ensure that the nation's health IT infrastructure supports activities that reduce medical errors, improve health care quality, improve public health activities, and facilitate the early identification and rapid response to public health threats and emergencies. 42 U.S.C. 300jj–11(b)(2) & (7).

[44] ONC, *HHS Health IT Patient Safety Action and Surveillance Plan* (July 2013), *http://www.healthit.gov/policy-researchers-implementers/health-it-and-patient-safety* (hereinafter ''Health IT Safety Plan''). The first objective of the Health IT Safety Plan is to use health IT to make care safer. *See id.* at 7. The Plan specifically contemplates that ONC will update its standards and certification criteria to improve safety-related capabilities and add new capabilities that enhance patient safety.

[45] 78 FR 58786.

[46] 21 U.S.C. 360i(f).

[47] See FDA, Global Unique Device Identification Database (GUDID) Guidance for Industry and Food and Drug Administration Staff (June 27, 2014), available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM369248.pdf.*

[48] Pursuant to 21 U.S.C. 360i(f), FDA must implement the Unique Device Identification System Final Rule with respect to devices that are implantable, life-saving, and life sustaining not later than 2 years after the rule was finalized. Other implementation and compliance dates are detailed in the final rule. Compliance dates for UDI implementation will be phased in based on the existing risk-based classification of medical devices: September 2014 for devices classified by FDA at the highest risk level (Class III); September 2015 for implantable, life-supporting or life-sustaining devices; September 2016 for moderate risk (Class II) devices; and September 2018 for low risk (Class I) devices.

[49] For a detailed summary of the comments we received on our earlier implantable device list proposal, see the 2014 Edition, Release 2, final rule (79 FR 54458).

[50] 79 FR 54458.

Unique Device Identification System to protect patient safety and improve health care quality and efficiency. Crucially, recording and exchanging UDIs in patients' electronic health records would enable this information to travel with patients as they move among providers and throughout the health care system. With access to this information at the point of care, clinicians can accurately identify a patient's implantable devices and prevent adverse events resulting from misidentification or non-identification of the device and its associated safety characteristics (such as MRI compatibility and latex content). Health IT could also be leveraged in conjunction with automated identification and data capture (AIDC) or other technologies to streamline the capture and exchange of UDIs and associated data for patients' devices. As UDIs become ubiquitous, UDI capabilities in health IT could facilitate better post-market surveillance of devices, better and more accurate reporting of device-related events, and more effective corrective and preventative action in response to device recalls and alerts.

Fully implementing UDIs will take time and require addressing a number of challenges. A key challenge is that UDIs may initially be captured in any of a variety of clinical, inventory, registry, or other IT systems. Robust adoption and use of UDIs will require bridging these different components and changing IT and administrative processes to, among other things, ensure that UDIs are properly captured and associated with patients' electronic health records.

In December 2014, the Brookings Institution with collaboration from FDA published a detailed roadmap for effective UDI implementation.[51] Significantly, the roadmap's recommendations stated that ''while the path to full implementation is complex, there are relatively straightforward steps that can be done now'' to begin realizing the benefits of UDI implementation across the health care system. The roadmap's recommendations specifically urged ONC to support the incorporation of UDIs into certification criteria for health IT.

We agree that a key initial step towards solving these challenges is incorporating UDIs in certified health IT. We believe now is the appropriate time to take that first step. Major efforts have been underway for some time to harmonize and pilot health IT standards and specifications in support of a variety of UDI use cases, and substantial progress has been achieved to standardize the electronic exchange of UDIs.[52] In addition, FDA plans to implement the GUDID in early 2015 and require UDIs for all implantable devices by September 2015.[53] In light of this progress on technical standards and FDA's timeline for UDI implementation, we believe it is feasible for health IT developers to begin implementing the baseline functionality necessary to use and exchange UDIs, and in particular for UDIs associated with patient's implantable devices. Once implanted, these devices cannot be inspected with the naked eye and are therefore more susceptible to misidentification and resulting patient harm.

To meet this criterion, a Health IT Module would have to enable a user to record, change, and access a patient's implantable device list, which would consist solely of one or more UDIs associated with a patient's implantable devices. The Health IT Module would also have to be able to parse the following data elements from a UDI:

- Device Identifier;
- Batch/lot number;
- Expiration date;
- Production date; and
- Serial number.

In addition to parsing the UDI, a Health IT Module presented for certification would have to be able to retrieve the optional ''device description'' data element associated with the Device Identifier in the GUDID, if the data element has been populated. This could be accomplished using the GUDID's web interface, web services, downloadable module, or any other method of retrieval permitted under FDA's GUDID guidance.

For each UDI in a patient's implantable device list, a Health IT Module presented for certification would have to enable a user to access the UDI and the data elements identified above (including the ''device description,'' if it exists). Also, in addition to enabling a user to record and access UDIs for a patient's implantable devices and as noted above, a Health IT Module would be required to provide the capability to change UDIs from a patient's implantable device list in order to meet this criterion. This functionality would allow a user to delete erroneous or duplicative entries from a patient's implantable device list and update the list in the event that a device were removed from the patient. We seek comment on whether such functionality is necessary and whether there is a safer or more effective way to maintain the accuracy of this information.

We believe that, in addition to capturing UDIs, health IT should facilitate the exchange of UDIs in order to increase the overall availability and reliability of information about patients' implantable and other devices. Therefore, we propose in a later section of this rule to include the 2015 Edition ''implantable device list'' certification criterion in the 2015 Edition Base EHR definition and propose to include a patient's unique device identifier(s) as data within the Common Clinical Data Set definition for certification to the 2015 Edition. Please see section III.B of this preamble for further discussion of these associated proposals.

We have also proposed to modify § 170.102 to include new definitions for ''Device Identifier,'' ''Implantable Device,'' ''Global Unique Device Identification Database (GUDID),'' ''Production Identifier,'' and ''Unique Device Identifier.'' This will prevent any ambiguity in interpretation and ensure that each term's specific meaning reflects the same meaning given to them in the Unique Device Identification System final rule and in 21 CFR 801.3. Capitalization was purposefully applied

[51] The Brookings Institution, *Unique Device Identifiers (UDIs): A Roadmap for Effective Implementation* (December 2014) (available at *http://www.brookings.http://www.brookings.edu/~/media/research/files/papers/2014/12/05%20medical%20device%20tracking%20system/udi%20final%2012052014*).

[52] For example, the Brookings Institution and FDA convened a UDI Implementation Work Group comprising device manufacturers, payers, health IT developers, academics, clinicians, and other stakeholders to explore opportunities and challenges associated with capturing UDIs in claims, identifying steps for implementation and integration of UDIs within EHRs and other health care IT infrastructure, and utilizing UDIs as a tool for improved patient and provider connectivity. *http://www.brookings.edu/about/centers/health/projects/development-and-use-of-medical-devices/udi.* The Work Group held a series of expert workshops and in December 2014 published a detailed roadmap for effective UDI implementation. The Brookings Institution, *Unique Device Identifiers (UDIs): A Roadmap for Effective Implementation* (December 2014) (available at http://www.brookings.http://www.brookings.edu/~/media/research/files/papers/2014/12/05%20medical%20device%20tracking%20system/udi%20final%2012052014). Concurrently, the HL7 Technical Steering Committee has established a UDI Task Force to ensure that UDI is implemented in a consistent and interoperable manner across the suite of HL7 standards. See *http://hl7tsc.org/wiki/index.php?title=TSC_Minutes_and_Agendas.* And through an S&I Framework Structured Data Capture Initiative, ONC, AHRQ, FDA, and NLM are collaborating with industry stakeholders to include UDI data for devices in health IT adverse event reporting. See *http://wiki.siframework.org/Structured+Data+Capture+Initiative.* AHRQ has already incorporated UDI and associated data attributes in its Common Formats for adverse event reporting. See AHRQ Data Dictionary, Common Formats Hospital Version 1.2, at 87, available at *https://www.psoppc.org/c/document_library/get_file?p_l_id=375680&folderId=431263&name=DLFE-15061.pdf.*

[53] *http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm427496.htm*; see also 21 U.S.C. 360i(f).

to each word in these defined phrases in order to signal to readers that they have specific meanings. Please see section III.B of this preamble for further discussion of these associated proposals.

In several respects the scope of this proposed implantable device list criterion is narrower than the criterion we proposed in the Voluntary Edition proposed rule. We received comments in response to the Voluntary Edition proposed rule recommending clear standards and use cases for an ''implantable device list'' criterion. With consideration of these comments, unlike in the Voluntary Edition proposed rule, we do not propose that health IT certified to the 2015 Edition ''implantable device list'' criterion be required to exchange or display contextual information (such as a procedure note) associated with a UDI because we believe additional standards and use case development will be needed to support these capabilities. We request comment on whether we have overlooked the need for or feasibility of requiring this functionality.

We also do not propose any requirements on health IT to facilitate the ''capture'' of UDIs at the point of care. As discussed above, UDIs may initially be captured in any of a variety of clinical and non-clinical contexts, many of which are beyond the current scope of health IT certified under the ONC Health IT Certification Program. Prescribing a requirement for capturing UDIs in certified health IT would also be complicated by the range of data capture tools permitted under the UDI final rule, including several different types of AIDC technology. Moreover, as several commenters pointed out in response to our proposal in the Voluntary Edition proposed rule, only a subset of certified health IT users—generally surgeons or other clinicians who perform or assist with operations involving implantable devices—would have a need for such data capture functionality, and presumably health IT developers who specialize in health IT for these settings can develop appropriate solutions for these users.

Given the scope of our program and the current state of UDI adoption, we do not believe that it would be useful to address these ''upstream'' issues at this time through rulemaking. Hence our proposal focuses on: (1) Ensuring that certified health IT can record and exchange UDIs for implantable devices as part of a patient's core electronic health record using appropriate standards for interoperability and exchange so that regardless of how UDIs are captured, they can be readily integrated with patients' electronic health records; (2) providing all users of certified health IT with the ability to access basic information about patients' implantable devices, thereby promoting greater awareness of and stimulating additional demand for UDIs and UDI-related capabilities in health IT; and (3) encouraging health IT developers to begin implementing GUDID functionality. We believe that focusing on these three areas of baseline UDI functionality will provide the greatest value to our stakeholders and efforts to promote adoption of UDIs and realize the significant benefits of UDIs and FDA's Unique Device Identification System described in this proposal.

• *Social, Psychological, and Behavioral Data*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(21) (Social, psychological, and behavioral data)

We propose a new 2015 Edition ''social, psychological, and behavioral data'' certification criterion that would require a Health IT Module to be capable of enabling a user to record, change, and access a patient's social, psychological, and behavioral data based on SNOMED CT® and LOINC® codes. This would include the ability to record a patient's decision not to provide the information.

An individual's health is shaped largely by life circumstances that fall outside the traditional health care system and include social, psychological, and behavioral factors. These factors include, but are not limited to, family support systems, stress, housing, nutrition, income, and education. This proposed certification criterion to further the collection and use of such patient data is not intended to be comprehensive; rather, it reflects efforts to further HHS priorities to transform health delivery, to reduce health disparities, and to achieve the overarching goals of the National Quality Strategy. In particular, the proposed certification criterion supports efforts to reduce disparities and efforts to collect patient social, psychological, and behavioral data for improved health care, such as by aligning with recommendations from HHS and the Institute of Medicine.[54]

We believe that offering certification that would require a Health IT Module to enable a user to record, change, and access a patient's social, psychological, and behavioral data would assist a wide array of stakeholders (*e.g.,* providers, consumers, payors, community-based organizations, and state and local governments) in better understanding how this data may adversely affect health. Ultimately, this can lead to better health outcomes for these populations through improved patient care, quality improvement, health equity, and clinical decision support based on individual factors.

We also believe the self-reporting of information by individuals in response to the questions included in these social, psychological, and behavioral measures (*i.e.,* the question and answer sets below) could be utilized for the EHR Incentive Programs Stage 3 which proposes an objective on patient engagement, including patient-generated health data. For more information, please refer to the EHR Incentive Programs Stage 3 proposed rule published elsewhere in this issue of the **Federal Register**.

We have heard from many stakeholders recommending that we prioritize the use of available measures and instruments for the structured recording of social, psychological, and behavioral data, and have followed those recommendations here. The measures (questions and answers sets below) will have LOINC® codes (or in the case of sexual orientation and gender identity, SNOMED CT® codes for the answers—but no specific questions) used to identify them. Therefore, we propose, for certification to this criterion, that social, psychological, and behavioral data be coded in accordance with, at a minimum, version 2.50 of LOINC® as attributed in the table below.[55] Please note that some question-answer sets for specific domains do not currently have a LOINC® code in place; in these instances it is expected that LOINC® codes will be established in a newer version of LOINC® prior to the

[54] U.S. Department of Health and Human Services, Office of Minority Health, 2011, *HHS Action Plan to Reduce Racial and Ethnic Disparities: A Nation Free of Disparities in Health and Health Care* (available at: *http://www.minorityhealth.hhs.gov/npa/files/Plans/HHS/HHS_Plan_complete.pdf*); U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, 2011, *Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status* (available at: *http://aspe.hhs.gov/datacncl/standards/ACA/4302/index.pdf*); and Institute of Medicine (IOM), November 2014, Washington, DC, The National Academies Press, 2014, *Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2* (available at: *http://iom.edu/Reports/2014/EHRdomains2.aspx*).

[55] We refer readers to section III.A.2.d (''Minimum Standards'' Code Sets) for further discussion of our adoption of LOINC® as a minimum standards code set and our proposal to adopt version 2.50, or potentially a newer version if released before a subsequent final rule, as the baseline for certification to the 2015 Edition.

publication of a subsequent final rule. Please further note that we propose to include sexual orientation and gender identity within this certification criterion as described after this table.

Domain	Question(s) [LOINC® name]	Answer(s) [LOINC® answer code]	LOINC® Codes for question-answer list combination	LOINC® Answer list ID
Financial Resource Strain (Overall financial resource strain from CARDIA).	How hard is it for you to pay for the very basics like food, housing, medical care, and heating? Would you say it is . . .	For example: Very hard, Somewhat hard, Not hard, at all.[56]	LOINC® code pending.	LOINC® code pending.
Education (Educational attainment).	What is the highest level of school you have completed or the highest degree you have received? [57]	[0] Never attended/kindergarten only [1] 1st grade [2] 2nd grade [3] 3rd grade [4] 4th grade [5] 5th grade [6] 6th grade. [7] 7th grade. [8] 8th grade. [9] 9th grade. [10] 10th grade. [11] 11th grade. [12] 12th grade, no diploma. [13] High school graduate. [14] GED or equivalent. [15] Some college, no degree. [16] Associate degree: occupational, technical, or vocational program. [17] Associate degree; academic program. [18] Bachelor's degree (e.g., BA, AB, BS). [19] Master's degree (e.g., MA, MS, MEng, MEd, MSW, MBA). [20] Professional school degree (example: MD, DDS, DVM, JD). [21] Doctoral degree (example: PhD, EdD). [77] Refused. [99] Don't know.	63504–5	LL1069–5.
Stress (from Elo et al) [58]	Stress means a situation in which a person feels tense, restless, nervous, or anxious, or is unable to sleep at night because his/her mind is troubled all the time. Do you feel this kind of stress these days?	For example: Likert scale ranging from 1—indicating not at all, 2—a little bit, 3—somewhat, 4—quite a bit, to 5—indicating very much.	LOINC® code pending.	LOINC® code pending.
Depression (PHQ–2)	[Patient Health Questionnaire 2 item (PHQ–2) [Reported]].	N/A	55757–9	N/A.
	Little interest or pleasure in doing things in last 2 weeks [Reported.PHQ].	[0] Not at all, [1] Several days, [2] More than half the days, [3] Nearly every day.	44250–9	LL358–3.
	Feeling down, depressed or hopeless in last 2 weeks [Reported.PHQ].	[0] Not at all, [1] Several days, [2] More than half the days, [3] Nearly every day.	44255–8	LL358–3.
	[Patient Health Questionnaire 2 item (PHQ–2) total score [Reported]].	For example: 0–6	5578–7	Answer is in UCUM units.[59]
Physical Activity (Exercise Vital Signs).	How many days of moderate to strenuous exercise, like a brisk walk, did you do in the last 7 days? [SAMHSA].	For example: 1,2,3,4,5,6,7, etc.	68515–6	Answer is in UCUM units.[60]
	On those days that you engage in moderate to strenuous exercise, how many minutes, on average, do you exercise? [SAMHSA].	For example: 10, 20, etc.	68516–4	Answer is in UCUM units.
Alcohol Use (AUDIT–C)	[Alcohol Use Disorder Identification Test—Consumption [AUDIT–C].	N/A	72109–2	N/A.

Domain	Question(s) [LOINC® name]	Answer(s) [LOINC® answer code]	LOINC® Codes for question-answer list combination	LOINC® Answer list ID
	How often do you have a drink containing alcohol? [SAMHSA].	[a] Never [b] Monthly or less [c] 2–4 times a month [d] 2–3 times a week [e] 4 or more times a week	68518–0	LL2179–1.
	How many standard drinks containing alcohol do you have on a typical day? [SAMHSA].	[a] 1 or 2 [b] 3 or 4 [c] 5 or 6 [d] 7 to 9 [e] 10 or more	68519–8	LL2180–9.
	How often do you have six or more drinks on one occasion? [SAMHSA].	[a] Never [b] Less than monthly [c] Monthly [d] Weekly [e] Daily or almost daily	68520–6	LL2181–7.
	[Total score [AUDIT–C]]	N/A [61]		N/A.
Social Connection and Isolation (NHANES III).	Are you married or living together with someone in a partnership at the time of questioning? In a typical week, how many times do you talk on the telephone with family, friends, or neighbors? How often do you get together with friends or relatives? How often do you attend church or religious services? How often do you attend meetings of the clubs or organizations you belong to?	For example, these categories form an ordinal scale assessing the number of types of social relationships on which a person is connected and not isolated, and has standard scoring. Individuals receive one point for each of the following: Being married or living together with someone in a partnership at the time of questioning, averaging three or more social interactions per week (assessed with questions one and two, above), reporting attending church or other religious services more than four times per year (assessed with question three, above), and reporting that they belong to a club or organization (assess with question four, above). A score of 0 represents the highest level of social isolation and a score of 4 represents the lowest level of social isolation. [62]	LOINC® code pending.	LOINC® code pending.
Exposure to violence: Intimate partner violence (HARK 4Q).	Within the last year, have you been humiliated or emotionally abused in other ways by your partner or ex-partner? Within the last year, have you been afraid of your partner or ex-partner? Within the last year, have you been raped or forced to have any kind of sexual activity by your partner or ex-partner? Within the last year, have you been kicked, hit, slapped, or otherwise physically hurt by your partner or ex-partner?	Pending	LOINC® code pending.	LOINC® code pending.

We propose to require that a Health IT Module enable a user to record, change, and access a patient's sexual orientation and gender identity as part of this certification criterion. We propose that sexual orientation be coded in accordance with, at a minimum, the September 2014 Release of the U.S. Edition of SNOMED CT® [63] and HL7 Version 3 attributed as follows:

[56] The answer is then scored from a scale of 1 (very hard) to 3 (not at all), and unknown answers are scored as a negative number.

[57] LOINC® Component used for the table.

[58] Elo, A.-L., A. Leppänen, and A. Jahkola. 2003. Validity of a single-item measure of stress symptoms. *Scandanavian Journal of Work, Environment & Health* 29(6):444–451.

[59] Note that LOINC® provides a translation table at *https://loinc.org/downloads/usage/units* that enumerates the UCUM syntax for a subset of UCUM codes that are commonly used in health IT that may be a useful reference for stakeholders.

[60] Note that LOINC® provides a translation table at *https://loinc.org/downloads/usage/units* that enumerates the UCUM syntax for a subset of UCUM codes that are commonly used in health IT that may be a useful reference for stakeholders.

[61] The Alcohol Use Disorders Identification Test C (AUDIT–C) is scored on a scale of 0 to 12. Each of the three AUDIT–C questions has 5 answer choices with points ranging from 0 to 4. A screen is considered positive for unhealthy alcohol use or hazardous drinking if the AUDIT–C score is 4 or more points for men or 3 or more points for women.

[62] Pantell et al., 2013.

Sexual orientation	Code
Homosexual	SNOMED CT® 38628009.
Heterosexual	SNOMED CT® 20430005.
Bisexual	SNOMED CT® 42035005.
Other	HL7 V3 nullFlavor OTH.
Asked but unknown	HL7 V3 nullFlavor ASKU.
Unknown	HL7 V3 nullFlavor UNK.

We propose that gender identity be coded in accordance with, at a minimum, the September 2014 Release of the U.S. Edition of SNOMED CT® [64] and HL7 Version 3 attributed as follows:

Gender identity	Code
Identifies as male gender.	SNOMED CT® 446151000124109.*
Identifies as female gender.	SNOMED CT® 446141000124107.*
Female-to-male transsexual.	SNOMED CT® 407377005.
Male-to-female transsexual.	SNOMED CT® 407376001.
Identifies as non-conforming gender.	SNOMED CT® 446131000124102.*
Other	HL7 V3 nullFlavor OTH.
Asked but unknown	HL7 V3 nullFlavor ASKU

*These new concepts will appear in the March 2015 release of the U.S. Edition of SNOMED CT® and are now viewable at *https://uscrs.nlm.nih.gov/main.xhtml.*

We note that the functionality under consideration to record the data discussed above has no bearing on whether a patient chooses to provide this information or whether a health care provider chooses to record the information or would be required to do so through the EHR Incentive Programs or other programs. However, we believe the structured recording of these types of data as described is the best available method for reliably capturing and maintaining accurate reflections of this information. For this proposed certification criterion, we seek comment on whether:

- The appropriate measures have been included for the listed social, psychological, and behavioral data;
- There should be standardized questions associated with the collection of sexual orientation and gender identity data (and if so, what vocabulary standard would be best suited for coded these standardized questions);
- We should set a minimum number of data measures for certification (*e.g.,* at a minimum: One, 3, or all); and
- These measures should be part of one certification criterion or separate certification criteria. We note that our proposal for an ''Open Data Certified Health IT Products List,'' as discussed in section IV.D.3 of this preamble, would result in more granular identification of certified health IT. Specific to this criterion, the CHPL would include information regarding each of the data measures (*e.g.,* education, depression, and sexual orientation) that were certified as part of a Health IT Module's certification to this criterion.

Work Information—Industry/Occupation Data

The Institute of Medicine identified patients' work information as valuable data that could be recorded by health IT and used by both health care providers and public health agencies.[65] Similarly, the 2012 HHS Environmental Justice Strategy and Implementation Plan echoed the potential benefits of having work information in EHR technology.[66] The combination of industry and occupation (I/O) information provides opportunities for health care providers to improve patient health outcomes—for health issues wholly or partially caused by work and for health conditions whose management is affected by work. For example, ''Usual'' (longest-held) I/O information can be key for health care improvement and population-based health investigations, and is already a required data element for cancer reporting.[67] Health care providers also can use current I/O information to assess symptoms in the context of work activities and environments, inform patients of risks, obtain information to assist in return-to-work determinations, and evaluate the health and informational needs of groups of patients.

Since publication of the Voluntary Edition proposed rule (79 FR 10924) in which we requested comment on I/O information for the purposes of certification, we have considered health IT developer feedback on the need to adopt consensus standards for capturing I/O information in health IT and continue to work with the National Institute for Occupational Health and Safety (NIOSH) to explore avenues to record I/O data in health IT. NIOSH also continues to work with various industry stakeholders and health IT developers to assess the incorporation of patient I/O fields into commercial EHRs, develop occupationally related CDS, and to investigate practices and systems to achieve accurate, automated coding of I/O information. Given the value of I/O information as noted above and the progress being made by NIOSH and others, we are making a refined request for comments as part of a future edition of certification criteria. We invite commenters to consider what additional support might be needed for health IT developers, implementers, and users to effectively include a certification criterion that would require health IT to enable a user to record, change, and access (all electronically) the following data elements in structured format:

- Patients' employment status and primary activities (*e.g.,* volunteer work);
- Patients' current I/O, linked to one another and with time-stamp, including start date;
- Patients' usual I/O, linked to one another and with time-stamp, including start year and duration in years; and
- Patients' history of occupation with a time and date stamp for when the history was collected (to note, this is focused on the capability to record a history, not a requirement that a history must be recorded or that a patient history be recorded for a certain historical period of time).

We solicit public comment on the experience health IT developers and health care providers have had in recording, coding, and using I/O data. This would include any innovation that is making I/O data more useful for providers.

To better understand the health care needs associated with work data, we specifically solicit public comment from *health care providers, provider*

[63] We refer readers to section III.A.2.d (''Minimum Standards'' Code Sets) for further discussion of our adoption of SNOMED CT® as a minimum standards code set and our proposal to adopt the September 2014 Release (U.S. Edition), or potentially a newer version if released before a subsequent final rule, as the baseline for certification to the 2015 Edition.

[64] We refer readers to section III.A.2.d (''Minimum Standards'' Code Sets) for further discussion of our adoption of SNOMED CT® as a minimum standards code set and our proposal to adopt the September 2014 Release (U.S. Edition), or potentially a newer version if released before a subsequent final rule, as the baseline for certification to the 2015 Edition.

[65] IOM (Institute of Medicine). 2011. ''Incorporating Occupational Information in Electronic Health Records: A Letter Report''. Available at: *http://www.nap.edu/catalog.php?record_id=13207.*

[66] U.S. Department of Health and Human Services. February, 2012. 2012 HHS Environmental Justice Strategy and Implementation Plan. Available at: *http://www.hhs.gov/environmentaljustice/strategy.html.*

[67] CDC (2) (Centers for Disease Control and Prevention). 2012. Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA) Release 1.0, August 2012. Available at: *http://www.cdc.gov/phin/library/guides/Implementation_Guide_for_Ambulatory_Healthcare_Provider_Reporting_to_Central_Cancer_Registries_August_2012.pdf.*

organizations, and patients on the following:

- The usefulness for providers to be able to access current and usual I/O and related data in the EHR, including whether additional data elements, such as work schedule, are useful.
- The usefulness of a history of positions provided as current I/O, with data from each position time-stamped, linked, retained, and accessible as part of the longitudinal patient care (medical) record.
- Narrative text (vs. codes) for both current and usual I/O.
- CDC_Census codes for both current and usual I/O; available through PHIN VADS at *https://phinvads.cdc.gov/vads/SearchVocab.action.*
- SNOMED CT® codes for occupation (current codes or potentially developed codes).
- Other standards and codes that may be in use by the health IT industry for both current and usual I/O.

U.S. Uniformed/Military Service Data

In the Voluntary Edition proposed rule (79 FR 10924), we outlined rationale for a potential certification criterion that would assess the capability of health IT to enable a user to record, change, and access U.S. military service or all uniformed service (including commissioned officers of the U.S. Public Health Service (USPHS) and the National Oceanographic and Atmospheric Administration (NOAA) as they too are eligible for military health services, veterans benefits, and related services). We reiterate the rationale here as we continue to believe it is persuasive for adopting such a certification criterion. In recent years, U.S. Military service members have been returning from service in Iraq and Afghanistan and other various combat duty stations. A portion of these service members are returning with traumatic brain injuries, major limb injuries, and diagnoses of post-traumatic stress disorder as reported by the Department of Defense and Department of Veterans Affairs. We believe recording U.S. uniformed/military service information can have many benefits. It can help in identifying epidemiological risks for patients such as those noted above. It can assist in ensuring that a patient receives all the health care benefits he or she is entitled to by alerting medical professionals to the patient's service history, which can facilitate the coordination of benefits. This information can also increase the ability to assemble a longitudinal record of care for a U.S. service member, such as by requesting or merging of a patient's electronic health record stored by the Department of Defense, Veteran's Health Administration, and/or another health care provider.

In response to the request for comment on a ''U.S. uniformed/military service'' certification criterion in the Voluntary Edition proposed rule, commenters indicated that vocabulary standards for capturing such history may not be mature enough yet. Specifically, commenters noted that SNOMED CT® currently has relevant codes, such as ''history relating to military service,'' and ''duration of military service,'' but not codes to cover all potential military service statuses, capture military service in an unambiguous way (*e.g.,* capturing current employed as well as history of military service) and military service in foreign locales. To improve coding of military and all uniformed history, we believe a promising path forward would be to add codes to the U.S. Extension of SNOMED–CT®. Therefore, we request comment on the following:

- Whether a potential certification criterion should be focused solely on U.S. military service or all uniformed service members (*e.g.,* commissioned officers of the USPHS and NOAA);
- Whether the U.S. Extension of SNOMED–CT® is the most appropriate vocabulary code set or whether other vocabulary code sets may be appropriate; and
- The concepts/values we should use to capture U.S. military service or all uniformed service status. We ask commenters to consider the work of NIOSH on I/O information as it relates to capturing military service.

Other Social, Psychological, and Behavioral Data

We seek comment on whether there are additional social, psychological, and behavioral data that we should include for certification as well as the best available standards for representing such data.

- *Decision Support—Knowledge Artifact*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(22) (Decision support—knowledge artifact)

We propose a new ''decision support—knowledge artifact'' certification criterion in the 2015 Edition for technology to electronically send and receive clinical decision support knowledge artifacts in accordance with a Health eDecisions (HeD) standard.

A previous ONC-sponsored S&I initiative, HeD, defined two use cases (UC) with the goals of expressing CDS interventions in a standardized format for sharing (UC 1) and requesting/receiving knowledge artifacts from a CDS service provider (UC 2). We discuss UC 2 further in the proposal for a 2015 Edition ''decision support—service'' certification criterion in this section of the preamble. HeD UC 1 defined the functional requirements needed to build a standard schema for the contents of three ''CDS Knowledge Artifact'' [68] types: event condition action (ECA) rules, order sets, and documentation templates.[69] UC 1 was based on the scenario of a ''CDS Knowledge Artifact supplier'' making a computable CDS Knowledge Artifact available to a ''CDS Artifact integrator.'' For example, in accordance with the HeD standard, health IT could automatically integrate medication order sets based on best practice clinical guidelines in a machine-readable format without the need for human interpretation.

In the Voluntary Edition proposed rule, we proposed to adopt the HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1 (January 2013) (''HeD standard'').[70] We stated that the HeD standard would greatly assist the industry in producing and sharing machine-readable files for representations of clinical guidance. We did not adopt the HeD standard as we agreed with commenters that more clarity is needed regarding the HeD proposals (79 FR 54453).

As the HeD initiative has completed, a new S&I initiative has launched, the Clinical Quality Framework (CQF), which builds on the HeD work and expands the scope to harmonize both CDS and electronic clinical quality measurement (eCQM) standards. The CQF initiative has created an updated and more modular HeD implementation guide for sharing CDS artifacts, HL7 Version 3 Standard: Clinical Decision Support Knowledge Artifact Specification, Release 1.2 DSTU (July 2014).[71] The modularity allows for portions of the HeD standard Release 1.2 to be updated without requiring updates

[68] A CDS Knowledge Artifact is the encoding of structured CDS content as a rule to support clinical decision making in many areas of the health care system, including quality and utilization measures, disease outbreaks, comparative effectiveness analysis, efficacy of drug treatments, and monitoring health trends.

[69] HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1 (January 2013) (''HeD standard'').

[70] *http://wiki.siframework.org/file/detail/implementation_guide_working_final_042413_lse_uploaded-1.docx.*

[71] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=337.*

to the entire standard. As the CQF work continues, this more recent standard will be leveraged heavily to produce a harmonized clinical quality expression language for both CDS and eCQMs.

We continue to believe that the HeD standard would greatly assist the industry in producing and sharing machine readable files for representations of clinical guidance. We therefore propose to adopt the HL7 Version 3 Standard: Clinical Decision Support Knowledge Artifact Specification, Release 1.2 DSTU (July 2014) (''HeD standard Release 1.2'') at § 170.204(d)(1) and offer testing and certification for health IT demonstrate it can electronically send and receive a CDS artifact formatted in the HeD standard Release 1.2.

We solicited comment in the Voluntary Edition proposed rule on what we should test and certify to when it comes to testing and certification for acceptance and incorporation of CDS Knowledge Artifacts (79 FR 54453). Commenters suggested that we focus testing on a few types of CDS Knowledge Artifacts, but not on all possible types included in the HeD standard. We note that HHS is developing publicly available CDS interventions in HL7 draft standard formats,[72] including the HeD standard Release 1.2, that will be available at *www.ushik.org.* We welcome comment on specific types of CDS Knowledge Artifacts on which we should focus testing and certification to the HeD standard Release 1.2. We also invite comments on versions of standards we should consider as alternative options, or for future versions of this certification criterion, given the ongoing work to harmonize CDS and quality measurement standards as discussed under the ''CQM—record and export'' certification criterion later in this section of the preamble.

- *Decision Support—Service*

2015 Edition Health IT Certification Criterion
§ 170.315(a)(23) (Decision support—service)

We propose a new ''decision support—service'' certification criterion in the 2015 Edition for technology to electronically make an information request with patient data and receive in return electronic clinical guidance in accordance with the standard in accordance with an HeD standard.

A previous ONC-sponsored S&I initiative, HeD, defined two use cases (UC) with the goals of expressing CDS interventions in a standardized format for sharing (HeD UC 1) and requesting/receiving knowledge artifacts from a CDS service provider (HeD UC 2). We discuss HeD UC 1 further in the proposal for a 2015 Edition ''decision support—knowledge artifact'' certification criterion above. HeD UC 2 defines the interface requirements needed to send patient data and receive CDS guidance based on one scenario: a request for clinical guidance made to a CDS guidance supplier. The HeD S&I initiative considered the following interactions with a CDS guidance supplier: Drug dosing calculation; immunization forecasting; disease management; quality measure evaluation; transition of care support; test appropriateness scores (*e.g.,* radiology tests); prediction rule evaluation (*e.g.,* APACHE score, AHRQ Pneumonia Severity Index); and severity of illness assessment (*e.g.,* Charlson Index). The HeD initiative created the HL7 Implementation Guide: Decision Support Service, Release 1—US Realm DSTU (January 2014) (''Decision Support Service IG''),[73] which defines SOAP and REST web service interfaces for CDS guidance services.

We proposed to adopt the Decision Support Service IG in the Voluntary Edition proposed rule because the implementation of this IG would promote systems whereby a health care provider can send a query about a patient to a CDS guidance supplier and receive CDS guidance back in near real-time. Although we received general support for adopting the Decision Support Service IG, we did not adopt it because the 2014 Edition Release 2 final rule focused on the adoption and revision of a small number of 2014 Edition certification criteria that add flexibility and make improvements to the existing set of 2014 Edition certification criteria.

We are aware of a more recent release of the Decision Support Service IG, HL7 Implementation Guide: Decision Support Service, Release 1.1 (March 2014), US Realm DSTU Specification (''Release 1.1'').[74] Release 1.1 utilizes the latest available version of the HL7 Virtual Medical Record specification. Given the general support we received in the Voluntary Edition proposed rule, we propose to adopt the HL7 Implementation Guide: Decision Support Service, Release 1.1 (March 2014), US Realm DSTU Specification at § 170.204(e)(1) and offer testing and certification for health IT to demonstrate the ability to send and receive electronic clinical guidance according to the interface requirements defined in Release 1.1. We also invite comments on versions of standards we could consider as alternative options, or for future versions of this certification criterion, given the ongoing work to harmonize CDS and quality measurement standards as discussed under the ''CQM—record and export'' certification criterion later in this section of the preamble.

- *Transitions of Care*

2015 Edition Health IT Certification Criterion
§ 170.315(b)(1) (Transitions of care)

We propose to adopt a 2015 Edition certification criterion for ''transitions of care'' (ToC) that is a continuation and extension of the ToC certification criterion adopted as part of the 2014 Edition Release 2 final rule at § 170.314(b)(8). This proposed criterion also reflects the corresponding structural and clarifying changes that we adopted in the 2014 Edition Release 2 final rule that correspond to ''clinical information reconciliation and incorporation'' certification criterion also adopted as part of the 2014 Edition final rule.

Accordingly, the 2015 Edition ToC certification criterion we propose to adopt would include many of the same capabilities adopted at § 170.314(b)(8) with the exception of the following revisions and additions.

Updated C–CDA Standard

As expressed in the 2014 Edition final rule, the C–CDA standard is now the single standard permitted for certification and the representation of summary care records. It is also referenced in other proposed 2015 Edition certification criteria. Industry stakeholders have continued to work to improve and refine the C–CDA standard since the 2014 Edition final rule, including publishing additional guidance for its consistent implementation.[75] An updated version, HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft

[72] This site may also include CDS interventions formatted to the Quality Improvement and Clinical Knowledge Model (QUICK) standard which we discuss in the preamble for the ''Clinical quality measures—record and export'' certification criterion.

[73] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=334.*

[74] *http://www.hl7.org/documentcenter/public/standards/dstu/HL7_DSS_IG%20_R1_1_2014MAR.zip.*

[75] *http://wiki.siframework.org/Companion+Guide+to+Consolidated+CDA+for+MU2.*

Standard for Trial Use, Release 2.0,[76] which was balloted through 2014, includes the following changes, which we believe provide important clarifications and enhancements:

- Addition of new structural elements: new document sections and data entry templates:
  - New Document Templates for: Care Plan; Referral Note; Transfer Summary.
  - New Sections for: Goals; Health Concerns; Health Status Evaluation/Outcomes; Mental Status; Nutrition; Physical Findings of Skin.
  - New organizers and many new entries (*e.g.* Wound Observation).
- Some sections/entries were deprecated (*i.e.,* should no longer be used).
- Updates to (versioning of) template/section/entry object identifiers (OIDs).
  - This includes a new chapter describing HL7's approach to template versioning.
- Tighter data constraints/requirements.
  - For example, some data elements with a ''MAY'' requirement now have a ''SHOULD'' requirement. Likewise, some with a ''SHOULD'' requirement now have a ''MUST'' requirement.
- Updated Vocabulary/Value Set constraints.
  - For example: two SNOMED CT® codes were added to the Current Smoking Status value set and the Tobacco Use value set to support the 2014 Edition vocabulary requirements for patient smoking status.
  - NLM's Value Set Authority Center (VSAC) was named as reference for Value Sets used in C–CDA.

In the Voluntary Edition proposed rule, we proposed to adopt the C–CDA Release 2.0 standard and reference its use in the other certification criteria in which this standard would have also been applicable. At the time of that proposal, the C–CDA Release 2.0 had not yet completed its balloting cycle within HL7 and stakeholder comments on the Voluntary Edition proposed rule expressed concern related to the C–CDA Release 2.0 standard's stability. Given that the C–CDA Release 2.0 has completed balloting and is now published as the next C–CDA version, we believe that the continued attention it received through HL7 balloting has resulted in a standard that is the best available for adoption in this proposed rule and for future implementation in the coming years. Thus, we propose to adopt C–CDA Release 2.0 at § 170.205(a)(4) as part of this certification criterion. We note that compliance with the C–CDA Release 2 cannot include the use of the ''unstructured document'' document-level template for certification to this criterion.

To address a technical implementation challenge sometimes referred to as ''bilateral asynchronous cutover,'' (which is meant to convey the complexity of continued interoperability among exchange partners as each upgrades their health IT at different times and with different standards capabilities), we propose that the 2015 Edition ToC certification criterion reference both the C–CDA Release 1.1 and Release 2.0 standards. In other words, a Health IT Module presented for certification to this criterion would need to demonstrate its conformance and capability to create and parse both versions (Release 1.1 and 2.0) of the C–CDA standards. Under this proposal, the sending Health IT Module would send two documents (one conforming to C–CDA R1.1 and other conforming to C–CDA R2.0) and the receiving Health IT Module would receive both versions of the documents and choose the appropriate version for downstream processing.

While we recognize that this proposal is not ideal, we have proposed this more conservative approach as a way to mitigate the potential that there would be interoperability challenges for ToC as different health care providers adopt Health IT Modules certified to the 2015 Edition criterion at different times that include C–CDA Release 2.0 capabilities. However, we request public comment, especially from health IT developers with experience implementing the C–CDA, on an alternative approach related to the creation of C–CDA-formatted documents. The alternative approach would be focused on C–CDA creation and receipt capabilities related to whether the health IT system could produce one, ''dually compliant,'' C–CDA that addresses both C–CDA versions at once. We understand that this approach is possible, may be preferred from an implementation perspective, and could help prevent potential data duplication errors that could result if a Health IT Module is required to be able to produce two separate C–CDA files (one in each version) as part of certification.

Our proposal to adopt C–CDA Release 2.0 is applicable to all of the other certification criteria in which the C–CDA is referenced. Similarly, unless C–CDA Release 2.0 is explicitly indicated as the sole standard in a certification criterion, we propose to reference both C–CDA versions in each of these criteria for the reasons just discussed.

Valid/Invalid C–CDA System Performance

As we considered stakeholder feedback and reviewed the additional public dialogue surrounding the variability of CEHRT in recognizing valid/invalid documents formatted according to the C–CDA 1.1 standard, including structured content by different health IT developers,[77] we recognized that an expanded ToC certification criterion with a specific capability focused principally on health IT system behavior and performance related to recognizing valid/invalid C–CDAs would be beneficial. Thus, we propose to include within the 2015 Edition ToC certification criterion a specific focus on this technical system behavior. We believe this type of error checking and resilience is an important and necessary technical prerequisite in order to ensure that as data in the system is parsed from a C–CDA for incorporation as part of the ''clinical information reconciliation and incorporation'' certification criterion the user can be assured that the system has appropriately interpreted the C–CDA it received. Further, we believe this level of rigorous testing will better enable Health IT Modules to properly recognize C–CDA-based documents and prepare the necessary information for reconciliation and other workflow needs.

We propose that this specific aspect of the certification criterion would focus on and require the following technical outcomes be met. The Health IT Module would need to demonstrate the ability to detect valid and invalid C–CDA documents, including document, section, and entry level templates for data elements specified in 2014 and 2015 edition. Specifically, this would include:

- The ability of the Health IT Module to detect invalid C–CDA documents. Thus, any data in the submitted C–CDA document that does not conform to either the C–CDA 1.1 or 2.0 standard (in addition to data coding requirements specified by this regulation) would be considered invalid;
- The ability to identify valid C–CDA document templates (*e.g.,* CCD, Discharge Summary, Progress Note) and process the required data elements, section and entries, specific to the document templates and this regulation.
- The ability to detect invalid vocabularies and codes not specified in

[76] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=379.* Access to the IG is freely available for review during the public comment period by establishing an HL7 user account.

[77] D'Amore JD, et al. J Am Med Inform Assoc 2014;21:1060–1068.

either the C–CDA 1.1 or 2.0 standard or required by this regulation (*e.g.,* using a SNOMED CT® code where a LOINC® code is required or using a code which does not exist in the specified value set).

• The ability to correctly interpret empty sections and nullFlavor combinations per the C–CDA 1.1 or 2.0 standard. For example, we anticipate testing could assess a Health IT Module's ability to continue to process a C–CDA when a nullFlavor is used at the section template level.

We expect these capabilities would be tested by providing several C–CDA documents with valid and invalid data. We do not expect Health IT Modules presented for certification to have a common C–CDA handling process, however, we do expect that they would have a baseline capability to identify valid and invalid C–CDA documents and prepare the necessary data for clinical information reconciliation and incorporation. Further, we expect that Health IT Modules will have some mechanism to track errors encountered when assessing received C–CDA's and we have proposed that health IT be able to track the errors encountered and allow for a user to be notified of errors or review the errors produced. The Health IT Module would not need to support both and how this technical outcome is accomplished is entirely up to the health IT developer.

We direct readers to the proposed ''Consolidated CDA creation performance'' certification criterion (§ 170.315(g)(6)) under which we seek comment on a potential requirement for this certification criterion or the ''Consolidated CDA creation performance'' certification criterion that would evaluate the completeness of the data included in a C–CDA in order to ensure that the data recorded by health IT is equivalent to the data included in a created C–CDA.

XDM Package Processing

As indicated in the earlier paragraphs, a Health IT Module presented for certification to this certification criterion will need to support one of the edge protocols referenced in the Edge IG version 1.1 (*i.e.,* the ''IHE XDR profile for Limited Metadata Document Sources'' edge protocol or an SMTP-focused edge protocol (SMTP alone or SMTP in combination with either IMAP4 or POP3)). However industry feedback has indicated that the use of XDM packages has grown within the stakeholder community using Direct, which most often happens when Edge System A using XDR sends content and metadata to its HISP–A, who in turn packages that content and metadata into an XDM ZIP and sends it within a Direct message to HISP–B, which then ultimately sends the message containing the XDM package to Edge System B using an SMTP-based edge.

Therefore, if Edge System B does not support XDM package processing, interoperability could be impacted when HISP–B forwards XDM packages to Edge System B via the SMTP protocol. To mitigate this potential incompatibility, we propose to include a specific capability in this certification criterion that would require a Health IT Module presented for certification that is also being certified to the SMTP-based edge to demonstrate its ability to accept and process an XDM package it receives, which would include extracting relevant metadata and document(s). That is, this additional requirement only applies to a Health IT Module presented for certification with an SMTP-based edge implementation and not an XDR edge implementation). Additionally, because we expect XDM packaging to be created in accordance with the specifications included in IHE IT Infrastructure Technical Framework Volume 2b (ITI TF–2b),[78] we propose to adopt this as the standard (at § 170.205(p)(1)) for assessing whether the XDM package was successfully processed.

Common Clinical Data Set

We propose to include an updated Common Clinical Data Set for the 2015 Edition that includes references to new and updated vocabulary standards code sets. Please also see the Common Clinical Data Set definition proposal in section III.B.3 of this preamble.

Encounter Diagnoses

For encounter diagnoses, we are carrying over the requirement from the 2014 Edition ''ToC'' certification criterion that a Health IT Module must enable a user to create a transition of care/referral summary that also includes encounter diagnoses using either SNOMED CT® (September 2014 Release of the U.S. Edition as a baseline for the 2015 Edition) or ICD–10 codes.

''Create'' and Patient Matching Data Quality

In 2011, both the HITPC and HITSC made recommendations to ONC on patient matching. The HITPC made recommendations in the following five categories: Standardized formats for demographic data fields; internally evaluating matching accuracy; accountability; developing, promoting and disseminating best practices; and supporting the role of the individual/patient.[79] The HITSC made the following four recommendations: Detailing patient attributes that could be used for matching (in order to understand the standards that are needed); data quality; formats for these data elements; and what data are returned from a match request.[80] The standards recommended by the HITSC are as follows:

• *Basic Attributes:* Given Name; Last Name; Date of Birth; Administrative Gender.[81]

• *Other Attributes:* Insurance Policy Number; Medical Record Number; Social Security Number (or last 4 digits); Street Address; Telephone Number; Zip Code.

• *Potential Attributes:* Email Address; Voluntary Identifiers; Facial Images; Other Biometrics.

In July 2013, ONC launched an initiative to reinvigorate public discussion around patient matching, to perform a more detailed analysis of patient matching practices, and to identify the standards, services, and policies that would be needed to implement the HITPC and HITSC's recommendations. The initiative's first phase focused on a common set of patient attributes that could be leveraged from current data and standards referenced in our certification criteria. Given the initial findings, we proposed to include a limited set of standardized data as a part of the ''Create'' portion of the ToC criterion in the Voluntary Edition proposed rule to improve the quality of the data included in outbound summary care records. Overall, the vast majority of commenters supported the proposed policy that standardized patient attributes should be required for use in as part of the transitions of care certification criterion. Commenters overwhelmingly supported the inclusion of the proposed constrained specifications for last name/family name, maiden name, suffix, first/given name, middle/second name, maiden name, date of birth, current address and historical address, phone number, and sex in support of patient matching. However, given our approach in the 2014 Edition Release 2 final rule

[78] *http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_Rev7-0_Vol2b_FT_2010-08-10.pdf.*

[79] *http://www.healthit.gov/sites/default/files/hitpc-transmittal-letter-priv-sectigerteam-020211.pdf.*

[80] *http://www.healthit.gov/FACAS/sites/default/files/standards-certification/8_17_2011Transmittal_HITSC_Patient_Matching.pdf.*

[81] Despite its inclusion of the word ''gender,'' ''Administrative Gender'' is generally used in standards to represent a patient's ''sex,'' such as male or female. See: *http://ushik.ahrq.gov/ViewItemDetails?system=hitsp&itemKey=83680000.*

to only adopt a small subset of the proposed certification criteria to provide flexibility, clarity, and enhance health information exchange, we decided not adopted this proposal.

We again propose to include a limited set of standardized data as a part of the ''Create'' portion of the ToC criterion in the 2015 Edition to improve the quality of the data included in outbound summary care records. To be clear, this proposal does *not* require a Health IT Module to capture the data upon data entry, but rather at the point when the data is exchanged (an approach commonly used for matching in HL7 transactions, IHE specifications,[82] C–CDA specification, and the eHealth Exchange). The proposed standardized data include: first name, last name, middle name (including middle initial), suffix, date of birth, place of birth, maiden name, phone number, and sex. In the bulleted list below, we identify more constrained specifications for some of the standardized data we propose. Based on our own research, we do not believe that the proposed constraints to these data conflict with the C–CDA. That being said, some proposed constraints may further restrict the variability as permitted by existing specifications and others may create new restrictions that do not currently exist within the C–CDA. We propose that:

- For ''last name/family name'' the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0 [83] (which addresses whether suffix is included in the last name field) be followed.
- For ''suffix,'' that the suffix should follow the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0 (JR, SR, I, II, III, IV, V, RN, MD, Ph.D., ESQ) [84] and that if no suffix exists, the field should be marked as null.
- For ''date of birth,'' that the year, month and date of birth should be required fields while hour, minute and second should be optional fields. If hour, minute and second are provided then either time zone offset should be included unless place of birth (city, region, country) is provided; in the latter local time is assumed. If date of birth is unknown, the field should be marked as null.
- For ''phone numbers,'' the ITU format specified in ITU–T E.123 [85] and ITU–T E.164 [86] be followed and that the capture of home, business, and cell phone numbers be allowed.[87] Further, that if multiple phone numbers are present in the patient's record, all should be included in the C–CDA and transmitted.
- For ''sex'' we propose to require developers to follow the HL7 Version 3 Value Set for Administrative Gender and a nullFlavor value attributed as follows: M (Male), F (Female), and UNK (Unknown).

While the Patient Matching Initiative's recommendations included standardizing current and historical address, we have not included a specific standardized constraint for that data at this time due to a lack of consensus around the proper standard. In response to the Voluntary Edition proposed rule, commenters also suggested that we delay support for international standards for address until future editions of certification criteria. To reiterate, the data we propose for patient matching would establish a foundation based on leveraging current data and standards in certification criteria. We welcome comments on this approach and encourage health IT developers to consider and support the use other patient data that would improve patient matching for clinical care and many types of clinical research.

Direct Best Practices

In the past couple of years we have heard feedback from stakeholders regarding health IT developers limiting the transmission or receipt of different file types via Direct. We wish to remind all stakeholders of the following best practices for the sharing of information and enabling the broadest participation in information exchange with Direct: *http://wiki.directproject.org/Best+Practices+for+Content+and+Workflow.*

Certification Criterion for C–CDA and Common Clinical Data Set Certification

We note that no proposed 2015 Edition health IT certification criteria includes just the C–CDA Release 2.0 and/or the Common Clinical Data Set, particularly with the 2015 Edition not including a proposed ''clinical summary'' certification criterion as discussed later on in this preamble. Health IT certified to simply the C–CDA Release 2.0 with or without certification to the Common Clinical Data Set may be beneficial for other purposes, including participation in HHS payment programs. We request comment on whether we should adopt a separate 2015 Edition health IT certification criterion for the voluntary testing and certification of health IT to the capability to create a summary record formatted to the C–CDA Release 2.0 with or without the ability to meet the requirements of the Common Clinical Data Set definition.

C–CDA Data Provenance Request for Comment

As the exchange of health data increases, so does the demand to track the provenance of this data over time and with each exchange instance. Confidence in the authenticity, trustworthiness, and reliability of the data being shared is fundamental to robust privacy, safety, and security enhanced health information exchange. The term ''provenance'' in the context of health IT refers to evidence and attributes describing the origin of electronic health information as it is captured in a health system and subsequently persisted in a way that supports its lifespan. As described in the President's Council of Advisors on Science and Technology (PCAST) Report ''Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans'' [88], provenance includes information about the data's source and the processing that the data has undergone. The report refers to ''tagged data elements'' as units of data accompanied by a ''metadata tag'' that describes the attributes, provenance, and required security protections of the data.

In April 2014, ONC launched the Data Provenance Initiative within the Standards and Interoperability (S&I) Framework to identify the standards necessary to capture and exchange provenance data, including provenance at time of creation, modification, and time of exchange.[89] The stakeholder community represented a wide variety of organizations including health IT developers; federal, state, and local agencies; healthcare professionals; research organizations; payers; labs; and individuals within academia. In the fall of 2014, the HL7 IG for CDA Release 2: Data Provenance, Release 1 (US Realm) (DSTU) [90] was published. This IG

[82] *http://www.ihe.net/Technical_Frameworks/.*

[83] *http://www.caqh.org/pdf/CLEAN5010/258-v5010.pdf.*

[84] *http://www.caqh.org/pdf/CLEAN5010/258-v5010.pdf.*

[85] *http://www.itu.int/rec/T-REC-E.123-200102-I/e.*

[86] *http://www.itu.int/rec/T-REC-E.164-201011-I/en.*

[87] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=186.*

[88] PCAST Report to the President: Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward, *http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf.*

[89] *http://wiki.siframework.org/Data+Provenance+Initiative.*

[90] *http://wiki.hl7.org/index.php?title=HL7_Data_Provenance_Project_Space* and *http://*

clarifies existing content from various standards within HL7 [91] and describes how provenance information for a CDA document in a health IT system should be applied, and what vocabulary should be used for the metadata. This includes provenance metadata in the CDA at the header, section and entry levels. We seek comment on the maturity and appropriateness of this IG for the tagging of health information with provenance metadata in connection with the C–CDA. Additionally, we seek comment on the usefulness of this IG in connection with certification criteria, such as ToC and VDT certification criteria.

• *Clinical Information Reconciliation and Incorporation*

2015 Edition Health IT Certification Criterion
§ 170.315(b)(2) (Clinical information reconciliation and incorporation)

We propose to adopt a 2015 Edition ''clinical information reconciliation and incorporation'' certification criterion that is a revised (but largely similar to the 2014 Edition Release 2) version of the ''clinical information reconciliation and incorporation'' criterion adopted at § 170.314(b)(9).

Incorporation System Performance

As we considered public comments made after the 2014 Edition final rule and reviewed the additional public dialogue surrounding the variability of certified health IT in incorporating C–CDAs including structured content by different health IT developers [92], we recognized the need to expand the existing ''clinical information reconciliation and incorporation'' certification criterion to focus on health IT system behavior and performance related to incorporating C–CDAs including structured content. We believe that testing a Health IT Module's capability to reconcile and incorporate, at a minimum: problems, medications, and medication allergies from multiple C–CDAs will improve the overall clinical effectiveness.

We expect that testing for this specific system performance would include the ability to incorporate valid C–CDAs with variations of data elements to be reconciled (*e.g.*, documents with no medications, documents having variations of medication timing data). In addition we believe we can further strengthen this certification criterion by proposing to require that a C–CDA be created based on the reconciliation and incorporation process in order to validate the incorporation results. We anticipate that the generated C–CDA would be verified using test tools for conformance and can be checked against the information that was provided to incorporate.

Accordingly, we propose that the following technical system behavior and performance also be addressed as part of the clinical information reconciliation and incorporation certification criterion: The Health IT Module must demonstrate the ability to reconcile problem, medication, and medication allergy data from valid C–CDAs (both Release 1.1. and 2.0) with variations of data elements to be reconciled and then generate a conformant C–CDA document based on the reconciled information. For example, a test could include assessing a Health IT Module's capability to reconcile and incorporate medication information with different timing information.

• *Electronic Prescribing (e-Prescribing)*

2015 Edition Health IT Certification Criterion
§ 170.315(b)(3) (Electronic prescribing)

We propose to adopt a 2015 Edition certification criterion for e-prescribing that is revised in comparison to the 2014 Edition ''e-prescribing'' criterion (§ 170.314(b)(3)). First, for the purposes of certification, we propose to require a Health IT Module to be able to receive and respond to additional NCPDP SCRIPT Standard Implementation Guide Version 10.6 (v10.6) transactions or segments, namely Change Prescription, Refill Prescription, Cancel Prescription, Fill Status, and Medication History. Second, for the purposes of certification, we propose to require that a Health IT Module demonstrate that directions for medication use transmitted as e-prescriptions are codified in a structured format. Third, for the purposes of certification, we propose to require a Health IT Module be able to limit a user to e-prescribing all medications in the metric unit standard only, follow NCPDP-recommended conventions for use of leading zeroes before a decimal, and avoid use of trailing zeroes after a decimal when e-prescribed.

e-Prescribing Transactions or Segments

For 2014 Edition testing and certification to this criterion, a Health IT Module presented for certification must demonstrate that it can create a new prescription according to the NCPDP SCRIPT v10.6 New Prescription transaction (NEWRX). Stakeholders have recommended we consider expanding testing to a greater number of NCPDP SCRIPT v10.6 transactions and segments in order to better facilitate prescriber and pharmacist communications to provide better care for patients. Stakeholders have indicated that there is variable uptake and inconsistent implementation of the transactions in the NCPDP SCRIPT Standard v10.6 despite their added value for patient safety and improved communication between prescribers and pharmacists. In consideration of stakeholder input, we propose to include additional NCPDP SCRIPT v10.6 transactions in addition to the New Prescription transaction for health IT testing and certification. We propose that testing and certification would require a Health IT Module to demonstrate the ability to send and receive end-to-end prescriber-to-receiver/sender-to-prescriber transactions (bidirectional transactions). The transactions and reasons for inclusion for testing and certification are outlined in Table 3 below.

gforge.hl7.org/gf/project/cbcc/frs/?action=FrsReleaseBrowse&frs_package_id=240.

[91] Standards including HL7 Clinical Documentation Architecture Release 2 (CDA R2), HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1, and HL7 Version 2 Vocabulary & Terminology Standards (all are normative standards).

[92] D'Amore JD, et al. J Am Med Inform Assoc 2014; 21:1060–1068.

TABLE 3—PROPOSED ADDITIONAL[93] NCPDP SCRIPT v10.6 TRANSACTIONS FOR TESTING AND CERTIFICATION TO E-PRESCRIBING CERTIFICATION CRITERION

NCPDP SCRIPT v10.6 transaction or segment	Use case(s)	Problem addressed/value in testing for certification
Change Prescription (RXCHG, CHGRES).	• Allows a pharmacist to request a change of a new prescription or a ''fillable'' prescription. • Allows a prescriber to respond to pharmacy requests to change a prescription.	Facilitates more efficient, standardized electronic communication between prescribers and pharmacists for changing prescriptions.
Cancel Prescription (CANRX, CANRES).	• Notifies the pharmacist that a previously sent prescription should be canceled and not filled.	Facilitates more efficient, standardized electronic communication between prescribers and pharmacists for cancelling prescriptions. • Sends the prescriber the results of a prescription cancellation request.
Refill Prescription (REFREQ, REFRES).	• Allows the pharmacist to request approval for additional refills of a prescription beyond those originally prescribed. • Allows the prescriber to grant the pharmacist permission to provide a patient additional refills or decline to do so.	Facilitates more efficient, standardized electronic communication between prescribers and pharmacists for refilling prescriptions.
Fill Status (RXFILL)	Allows the pharmacist to notify the prescriber about the status of a prescription in three cases: 1) to notify of a dispensed prescription, 2) to notify of a partially dispensed prescription, 3) to notify of a prescription not dispensed.	Allows the prescriber to know whether a patient has picked up a prescription, and if so, whether in full or in part. This information can inform assessments of medication adherence.
Medication History (RXHREQ, RXHRES).	• Allows a requesting entity to generate a patient-specific medication history request. • The responding entity can respond with a patient's medication history, including source, fill number, follow-up contact, date range, as information is available.	Allows a requesting entity to receive the medication history of a patient. A prescriber may use this information to perform medication utilization review, medication reconciliation, or other medication management to promote patient safety.

We solicit comment on including the proposed transactions and segments for testing and certification to this certification criterion as outlined in Table 3, and on the problems addressed/value in testing for certification. We also solicit comment on the following issues:

• Other NCPDP SCRIPT v10.6 transactions that should be considered for testing and certification, and for what use cases/value;

• What factors we should consider for end-to-end prescriber-to-receiver testing.

We also propose to adopt and include the February 2, 2015 monthly version of RxNorm in this criterion as the baseline version minimum standards code set for coding medications (see section III.A.2.d (''Minimum Standards'' Code Sets) of this preamble).

Structured and Codified ''Sig''

Medications can be e-prescribed using a free text format, and typically the instructions include the medication name, dose, route of administration, frequency of administration, and other special instructions. This set of prescribing instructions is referred to as the ''Sig.'' In a free text format, non-standard or conflicting language may be used that is not understood by the pharmacist filling the prescription. Where systems do facilitate creation of the Sig, some systems may auto-concatenate the field length and thus the tail end of the Sig is lost. This has implications for communication between prescribers and pharmacists as well as for patient safety. Prescribers and pharmacists may have to engage in back-and-forth communication to clarify what is intended in the Sig instructions. Therefore, there is an opportunity to streamline prescriber-pharmacist communication, allow more time for direct activities of patient care, and reduce confusion during the pharmacy verification and dispensing processes.

We are aware that the NCPDP SCRIPT v10.6 standard includes structured Sig segments that are used to codify the prescribing directions in a structured format.[94] Providing Sig instructions in a structured format promotes accurate, consistent, and clear communication of the prescribing information as intended by the prescriber.

In one study of the structured and codified Sig within NCPDP SCRIPT v10.5, the Sig format fully represented 95% of ambulatory prescriptions tested.[95] While we believe that the results of this study give an indication of the scope of the structured and codified Sig within NCPDP SCRIPT v10.5, we note that the Sig standard was tested in the lab environment and not with live end-users. Stakeholders have also indicated the limitations of the structured and codified Sig within NCPDP SCRIPT v10.6 to represent all Sig instructions, particularly complex Sigs requiring multi-step directions. For example, stakeholders have noted that the Sig segment within the NCPDP SCRIPT v10.6 standard limits the field length to 140 characters whereas later versions of the NCPDP SCRIPT standard (from v201311 onward) have expanded the character length to 1000. Despite these potential limitations, we see standardizing and codifying the majority of routine prescriptions as a means to promote patient safety as well as reduce disruptions to prescriber workflow through a reduction in pharmacy call-backs.

We note the flexibility to create complex unstructured Sigs remains through use of existing e-prescribing workflow and appropriate use of the free text field. There is, however, low uptake of structured Sig according to the NCPDP SCRIPT v10.6 standard, which includes a combination of mandatory and conditional structured Sig segments.

We believe that medication Sig instructions should be codified in a

[93] We are proposing to keep the ''New Prescription'' transaction for testing and certification.

[94] NCPDP's Structured and Codified Sig Format Implementation Guide v1.2 is adopted within SCRIPT v10.6.

[95] Liu H, Burkhart Q and Bell DS. Evaluation of the NCPDP Structured and Codified Sig Format for e-prescriptions. J Am Med Inform Assoc. 2011 Sep–Oct;18(5):645–51.

structured format for the benefits outlined above. Therefore, we propose to require that a Health IT Module enable a user to enter, receive, and transmit codified Sig instructions in a structured format in accordance with NCPDP Structured and Codified Sig Format Implementation Guide v1.2 which is embedded within NCPDP SCRIPT v10.6 for certification to the e-prescribing criterion in the 2015 Edition.[96] We propose that this requirement apply to the New Prescription, Change Prescription, Refill Prescription, Cancel Prescription, Fill Status, and Medication History prescription transactions or segments as we understand that the NCPDP Structured and Codified Sig Format can be used for all NCPDP SCRIPT v10.6 prescription transactions that include the medication field. We also propose to require that a Health IT Module include all structured Sig segment components enumerated in NCPDP SCRIPT v10.6 (*i.e.,* Repeating Sig, Code System, Sig Free Text String, Dose, Dose Calculation, Vehicle, Route of Administration, Site of Administration, Sig Timing, Duration, Maximum Dose Restriction, Indication and Stop composites).

We are aware that NCPDP has recently published recommendations for implementation of the structured and Codified Sig format for a subset of component composites that represent the most common Sig segments in the NCPDP SCRIPT Implementation Recommendations Version 1.29.[97] We therefore welcome comment on this proposal, including whether we should require testing and certification to a subset of the structured and codified Sig format component composites that represent the most common Sig instructions rather than the full NCPDP Structured and Codified Sig Format Implementation Guide v1.2. As previously noted, prescribers would still be able to be able to create unstructured Sigs through the use of the free text field, and our proposal only discusses the capability of technology to enable a user to enter, receive, and transmit codified Sig instructions using the NCPDP Structured and Codified Sig Format.

Medication Dosing

In the Voluntary Edition proposed rule, we solicited comment on whether we should propose health IT certification for oral liquid medication dosing to the metric standard (*e.g.,* mL or milliliters) for patient safety reasons (79 FR 10926–10927). Use of the metric standard offers more precision in medication dose than the Imperial standard (*e.g.,* teaspoons), which can decrease preventable adverse drug events. A number of health care and standards developing organizations, including the AAP[98] and NCPDP,[99] support the use of the metric standard for dosing volumetric medications. Additionally, the FDA's Safe Use Initiative is working with CDC, NCPDP, and other stakeholders to encourage adoption of the NCPDP's recommendations for standardizing dosing designations on prescription container labels of oral liquid medications.[100] Recent research has demonstrated that parents who used milliliter-only dosing instruments were less likely to make dosing errors than parents who used teaspoons or tablespoon units.[101]

We received a number of comments to the comment solicitation. Many commenters noted that the structured Sig segment of the NCPDP SCRIPT Standard v10.6 supports use of the metric standard for liquid medication dosing. One ONC–ACB commented that in their experience, vendors have struggled to properly codify medication dosing information within the C–CDA in terms of consistency across all health IT systems. Many provider organizations and patient advocacy organizations were in support of requiring use of the metric standard for oral liquid medication dosing. Additionally, many commenters were in favor of providing the metric standard as one option to record liquid medication doses. We also received comments recommending the proper use of leading and trailing zeroes in dosing designations. NCPDP has recommended that dose amounts should always use leading zeroes before the decimal point for amounts less than one, and should not use trailing zeroes after a decimal point for oral liquid medications.[102]

Our intent is for health IT to be able to more precisely dose prescriptions in order to reduce dosing errors and improve patient safety. We also believe that use of the metric standard could improve patient safety and potentially reduce dosing errors for all medications in addition to oral liquid medications. We therefore propose, for certification to this criterion, that a Health IT Module be capable of limiting a user's ability to electronically prescribe all medications in only the metric standard. Prescription labels contain the dosing instructions specified by the prescriber. Thus, if the prescriber doses using the metric standard, the label will contain dosing instructions in the metric standard and potentially reduce dosing errors during administration. We also propose to require that a Health IT Module be capable of always inserting leading zeroes before the decimal point for amounts less than one when a user electronically prescribes medications as well as not allow trailing zeroes after a decimal point. We welcome comment on these proposals, including the feasibility of implementing the metric standard for e-prescribing all medications.

• *Incorporate Laboratory Tests and Values/Results*

2015 Edition Health IT Certification Criterion
§ 170.315(b)(4) (Incorporate laboratory tests and values/results)

We propose to adopt a 2015 Edition ''incorporate laboratory tests and values/results'' certification criterion that is revised in comparison to the 2014 Edition ''incorporate laboratory tests and values/results'' criterion (§ 170.314(b)(5)). We propose to adopt and include the HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Draft Standard for Trial Use, Release 2, US Realm (''LRI Release 2'') in the proposed 2015 Edition ''transmission of laboratory test reports'' criterion for the ambulatory setting. LRI Release 2 is currently under ballot reconciliation with HL7 and should be published in the next few months.[103] LRI Release 2 would:

• Implement common formats across US Realm IGs for consistent reader

[96] NCPDP's Structured and Codified Sig Format Implementation Guide v1.2 is within the NCPDP SCRIPT v10.6 standard.

[97] *http://www.ncpdp.org/NCPDP/media/pdf/SCRIPTImplementationRecommendationsV1-29.pdf.*

[98] AAP Council on Clinical Information Technology Executive Committee, 2011–2012. Policy Statement—Electronic Prescribing in Pediatrics: Toward Safer and More Effective Medication Management. Pediatrics 2013; 131;824.

[99] *http://www.ncpdp.org/NCPDP/media/pdf/wp/DosingDesignations-OralLiquid-MedicationLabels.pdf.*

[100] *http://www.fda.gov/Drugs/DrugSafety/SafeUseInitiative/ucm188762.htm#overdoses.*

[101] Unit of Measurement Used and Parent Medication Dosing Errors. Pediatrics 134:2 August 1, 2014. Pp. e354–e361.

[102] *http://www.ncpdp.org/NCPDP/media/pdf/wp/DosingDesignations-OralLiquid-MedicationLabels.pdf.*

[103] *http://www.hl7.org/participate/onlineballoting.cfm?ref=nav#nonmember.* Access to the current draft of the LRI Release 2 IG is freely available for review during the public comment period by establishing an HL7 user account.

experience (*e.g.,* sequence of sections, formatting, layout, and terminology);

- Incorporates all previous errata, LRI Release 1 DSTU comments and change requests;
- Adopt HL7 version 2.8 fields developed to fill gaps identified in the development of Release 1;
- Include harmonized data type ''flavors'' for use across the US Realm Lab IGs;
- Introduce initial requirements for error reporting conditions and severity (hard/soft errors) and system/application acknowledgements;
- Harmonize data element usage and cardinality requirements with LOI Release 1, and the electronic Directory of Services (eDOS) IG;
- Incorporate US Lab Realm value sets developed for clarity and consistency across all laboratory IGs; and
- Use a new publication method for value sets that allows for precision usage at point of use and provides ''at a glance'' comprehensive usage at the field and component-level across all laboratory IGs; and synced with value set activities (HL7, VSAC, etc.).

Overall, we propose to adopt LRI Release 2 because it addresses errors and ambiguities found in LRI Release 1 and harmonizes interoperability requirements with other laboratory standards we propose to adopt in this proposed rule (*e.g.,* the HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, DSTU Release 2, US Realm, 2013 [104]).

As compared to the 2014 Edition certification criterion, we also propose more specific requirements for how a Health IT Module must be capable of electronically displaying the information included in a test report. This specificity would improve the consistency with how laboratory tests and values/results are displayed, which would also assist with laboratory compliance with CLIA. To meet this criterion, a Health IT Module would be required to display the following information included in laboratory test reports it receives: (1) the information for a test report as specified in 42 CFR 493.1291(a)(1) through (a)(3) and (c)(1) through (c)(7); the information related to reference intervals or normal values as specified in 42 CFR 493.1291(d); the information for alerts and delays as specified in 42 CFR 493.1291(g) and (h); and the information for corrected reports as specified in 42 CFR 493.1291(k)(2).

We also propose, for the purposes of certification, to require a Health IT Module to be able to use, at a minimum, the version of Logical Observation Identifiers Names and Codes (LOINC®) adopted at § 170.207(c)(3) (version 2.50) as the vocabulary standard for laboratory orders. This is the most recent version of LOINC®. We refer readers to section III.A.2.d (''Minimum Standards'' Code Sets) for further discussion of our adoption of LOINC® as a minimum standards code set and our proposal to adopt version 2.50, or potentially a newer version if released before a subsequent final rule, as the baseline for certification to the 2015 Edition.

We propose to adopt the updated LRI Release 2 at § 170.205(j)(2), which requires the modification of the regulatory text hierarchy in § 170.205(j) to designate the standard referenced by the 2014 Edition version of this certification criterion at § 170.205(j) to be at § 170.205(j)(1). This regulatory structuring of the IGs would make the CFR easier for readers to follow.

EHR–S Functional Requirements LRI IG/Testing and Certification Requirements

We seek comment on the HL7 EHR–S Functional Requirements for the V2.5.1 Implementation Guide: S&I Framework Lab Results Interface R2, Release 1, US Realm, Draft Standard for Trial Use, Release 1 (''EHR–S IG''). The EHR–S IG is currently under ballot reconciliation with HL7.[105] The focus of the EHR–S IG is the definition of EHR system functional requirements related to the receipt of laboratory results that are compliant with the LRI Release 2. The EHR–S IG also includes additional requirements as set forth in CLIA as well as clinical best practices beyond the scope of LRI Release 2.

We specifically seek comment on the clarity and completeness of the EHR–S IG in describing the requirements related to the receipt and incorporation of laboratory results for measuring conformance of a Health IT Module to LRI Release 2. In addition, we seek comment on how a Health IT Module should be tested and certified consistently and uniformly for the incorporation of laboratory results data. For example, should testing and certification require the Health IT Module to demonstration the ability to associate the laboratory result with an order or patient, to recall the result for display or for submission to another technology, and/or to use the result for automated clinical decision support interventions? Further, what, if any, specific capabilities currently included in the EHR–S IG should be part of testing and certification for this criterion?

- Transmission of Laboratory Test Reports

2015 Edition Health IT Certification Criterion
§ 170.315(b)(5) (Transmission of laboratory test reports)

We propose to adopt a 2015 Edition ''transmission of laboratory test reports'' certification criterion that is revised in comparison to the 2014 Edition ''transmission of electronic laboratory tests and values/results to ambulatory providers'' criterion (§ 170.314(b)(6)). We have renamed this criterion to more clearly indicate its availability for the certification of health IT used by any laboratory. We propose to adopt and include the HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Draft Standard for Trial Use, Release 2, US Realm (''LRI Release 2'') in the proposed 2015 Edition ''transmission of laboratory test reports'' criterion. LRI Release 2 is currently under ballot reconciliation with HL7 and should be published in the next few months.[106] We propose to adopt this standard for the same reasons discussed in the 2015 Edition ''incorporate laboratory tests and values/results'' above. We refer readers to the description of the LRI Release 2 IG and our rationale for its adoption discussed in that criterion.

As also discussed in the 2015 Edition ''incorporate laboratory tests and values/results'' above, the LRI Release 2 IG requires the information for a test report as specified at 42 CFR 493.1291(a)(1) through (3), (c)(1) through (c)(7), (d), (g), (h) and (k)(2) to be included in the content message. Therefore, inclusion of this standard for certification should not only facilitate improved interoperability of electronically sent laboratory test reports (as discussed in more detail in the 2015 Edition ''incorporate laboratory tests and values/results'' criterion), but also facilitate laboratory compliance with CLIA as it relates to the incorporation and display of test results in a receiving system.

We also propose, for the purposes of certification, to require a Health IT

[104] We have proposed to adopt this implementation guide for the 2015 Edition ''CPOE for laboratory orders'' certification criterion.

[105] *http://www.hl7.org/participate/onlineballoting.cfm?ref=nav#nonmember.* Access to the current draft of the EHR–S IG is freely available for review during the public comment period by establishing an HL7 user account.

[106] Access to the current draft of the LRI Release 2 IG is freely available for review during the public comment period by establishing an HL7 user account.

Module to be able to use, at a minimum, the version of Logical Observation Identifiers Names and Codes (LOINC®) adopted at § 170.207(c)(3) (version 2.50) as the vocabulary standard for laboratory orders. This is the most recent version of LOINC®. We refer readers to section III.A.2.d (''Minimum Standards'' Code Sets) for further discussion of our adoption of LOINC® as a minimum standards code set and our proposal to adopt version 2.50, or potentially a newer version if released before a subsequent final rule, as the baseline for certification to the 2015 Edition.

We propose to adopt the updated LRI Release 2 at § 170.205(j)(2), which requires the modification of the regulatory text hierarchy in § 170.205(j) to designate the standard referenced by the 2014 Edition version of this certification criterion at § 170.205(j) to be at § 170.205(j)(1). This regulatory structuring of the IGs would make the CFR easier for readers to follow.

• *Data Portability*

2015 Edition Health IT Certification Criterion
§ 170.315(b)(6) (Data portability)

We propose to adopt a 2015 Edition ''data portability'' certification criterion that is revised in comparison to the 2014 Edition ''data portability'' certification criterion (§ 170.314(b)(7)). Similar to the 2014 Edition version, we propose to include the 2015 Edition ''data portability'' criterion in the Base EHR definition (*i.e.,* the 2015 Base EHR definition).

For the 2014 Edition ''data portability'' criterion, we expressed that the criterion was intended to enable an EP, eligible hospital, or CAH to create a set of export summaries for all patients in EHR technology formatted according to the C–CDA that includes each patient's most recent clinical information. (77 FR 54193). We also included this criterion in the Base EHR definition as a way to ensure that the capability was delivered to EPs, eligible hospitals, or CAHs. By including the criterion in the Base EHR definition, an EP, eligible hospital, or CAH must have EHR technology certified to this criterion in order to possess EHR technology that meets the CEHRT definition.

In the years since the 2014 Edition final rule was issued (September 2012) and the subsequent implementation and use of this capability by EPs, eligible hospitals, and CAHs, we have received two types of feedback. From health IT developers, we have received requests for clarification about this certification criterion's scope. For example, requests for clarifications about the data that must be produced and from how far back in time the data must be produced. Whereas from providers (and the implementation professionals and third party developers with which they work), we have generally received more substantive critiques about the overall usefulness of the capability and the ways in which health IT developers met the certification criterion's requirements but did not necessarily deliver on its intent. Such ''user'' comments conveyed that some health IT developers provided a capability that was difficult or non-intuitive to use, difficult to find to even use (*e.g.,* ''hidden''), and in some cases either required developer personnel to assist the provider in executing the capability or limited its execution to only being done by the developer at the provider's request. We have also received feedback that the scope of testing has not rigorously assessed the ability of health IT to create large quantities of export summaries. As a result, some providers have reported challenges and poor performance associated with this capability.

We believe that this feedback from CEHRT users indicates that the data portability certification criterion adopted in the 2014 Edition has not provided the data accessibility to providers we believed would occur as a result of its adoption. It also indicates that some health IT developers have (intentionally or unintentionally) obstructed the certification criterion's true intent—to give providers easy access and an easy ability to export clinical data about their patients for use in a different EHR technology or even a third party system for the purpose of their choosing.

To address provider critiques as well as to provide additional developer requested clarity, we propose a revised 2015 Edition ''data portability'' certification criterion as compared to the 2014 Edition version. The proposed data portability certification criterion at § 170.315(b)(6) approaches data portability from a slightly different angle than the 2014 Edition version and focuses on the following specific capabilities.

1. As a general rule, we emphasize that this capability would need to be user-focused and user driven. A user must be able to set the configuration options included within the more detailed aspects of the criterion and a user must be able to execute these capabilities at any time the user chooses and without subsequent developer assistance to operate. We expect that testing of a Health IT Module presented for certification to this criterion would include a demonstration that the Health IT Module enables a user to independently execute this capability without assistance from the health IT developer beyond normal orientation/training.

2. The criterion would require that a user be able to configure the Health IT Module to create an export summary for a given patient or set of export summaries for as many patients selected. It would also require that these export summaries be able to be created according to any of the following document-template types included in the C–CDA R2.0 (also proposed as the content standard in this criterion): CCD; Consultation Note; History and Physical; Progress Note; Care Plan; Transfer Summary; and Referral Note. We also propose that the Discharge Summary document template be included for a Health IT Module developed for the inpatient setting.

3. From a data perspective, we propose that the minimum data that a Health IT Module must be capable of including in an export summary are: the data represented by the Common Clinical Data Set and:

• Encounter diagnoses (according to the standard specified in § 170.207(i) (ICD–10–CM) or, at a minimum, the version of the standard at § 170.207(a)(4) (September 2014 Release of the U.S. Edition of SNOMED CT®) [107];

• Cognitive status;

• Functional status;

• For the ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information; and

• For the inpatient setting only. Discharge instructions.

4. We propose that a user would need to be able to be able to configure the technology to set the time period within which data would be used to create the export summary or summaries. And that this must include the ability to enter in a start and end date range as well as the ability to set a date at least three years into the past from the current date.

5. We propose that a user would need to be able to configure the technology to create an export summary or summaries based on the following user selected events:

• A relative date or time (*e.g.,* the first of every month);

[107] We refer readers to section III.A.2.d (''Minimum Standards'' Code Sets) for further discussion of our adoption of SNOMED CT® as a minimum standards code set and our proposal to adopt the September 2014 Release (U.S. Edition), or potentially a newer version if released before a subsequent final rule, as the baseline for certification to the 2015 Edition.

• A specific date or time (*e.g.,* on 10/24/2015); and

• When a user signs a note or an order.

6. We propose that a user would need to able to configure and set the storage location to which the export summary or export summaries are intended to be saved.

Again, we emphasize that all these capabilities would need to be able to be configured and executed by a user without the aid of additional health IT developer personnel and without the need to request developer action. Further, we also reiterate that we have expanded the nature and focus of this criterion to more precisely address provided critiques as well as to expand the anticipated and potential uses providers can deploy based on this more configuration focused criterion.

• Data Segmentation for Privacy

We propose to adopt two new certification criteria that would focus on the capability to separately track (''segment'') individually identifiable health information that is protected by rules that are more privacy-restrictive than the HIPAA Privacy Rule. This type of health information is sometimes referred to as sensitive health information. The HIPAA Privacy Rule serves as the federal baseline for health information privacy protections. It also generally permits the use or disclosure of protected health information (PHI) for limited specific purposes (such as treatment and payment) without a patient's permission.[108]

The HIPAA Privacy Rule does not override (or preempt) more privacy-protective federal and state privacy laws. A number of federal and state health information privacy laws and regulations are more privacy-protective than the HIPAA Privacy Rule. Typically, these rules require a patient's permission (often referred to as ''consent'' in these rules) in writing in order for the individually identifiable health information regulated by those laws to be shared. One example is the Federal Confidentiality of Alcohol and Drug Abuse Patient Records regulations (42 CFR part 2) (''part 2'') that apply to information about treatment for substance abuse from federally funded programs.[109] There are also federal laws protecting certain types of health information coming from covered U.S. Department of Veterans Affairs facilities and programs (38 U.S.C. 7332). These laws and comparable state laws were established, in part, to address the social stigma associated with certain medical conditions by encouraging people to get treatment and providing them a higher degree of control over how their health information may be shared. These laws place certain responsibilities on providers to maintain the confidentiality of such information. More restrictive state laws also protect certain categories of individually identifiable health information, such as information regarding minors or teenagers, intimate partner/sexual violence, genetic information, and HIV-related information.[110] These laws and regulations remain in effect and changes to these laws and regulations are not within the scope of this proposed rule.[111] However, with these laws in mind, the proposals that follow seek to encourage the development and use of a technical capability that permits users to comply with these existing laws and regulations. These proposals are also in line with the *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Version 1.0.*[112] HHS is committed to encouraging the development and use of policy and technology to advance patients' rights to access, to amend, and to make choices for the disclosure of their electronic individually identifiable health information. HHS also noted support for the development of standards and technology to facilitate patients' ability to control the disclosure of specific information that is considered by many to be sensitive in nature (such as information related to substance abuse treatment, reproductive health, mental health, or HIV) in an electronic environment.[113]

Technological advances are creating opportunities to share data and allow patient preferences to electronically persist in health IT. In 2012, ONC launched the Data Segmentation for Privacy (DS4P) initiative through ONC's Standards and Interoperability (S&I) Framework.[114] The DS4P initiative aimed to provide technical solutions and pilot implementations to help meet existing legal requirements in an increasingly electronic environment.[115] The DS4P initiative worked to enable the implementation and management of varying disclosure policies in an electronic health information environment in an interoperable manner. Overall, the DS4P initiative and its subsequent pilots focused on the exchange of health information in the context of 42 CFR part 2 and sought to develop technical standards that would enable a provider to adopt health IT that could segment electronic sensitive health information regulated by more restrictive laws and make compliance with laws like Part 2 more efficient. Since the sunset of the DS4P initiative in April 2014, there have been live implementations and public testimony regarding the success and practical application of the DS4P standard. Organizations including the Substance Abuse and Mental Health Services Administration (SAMHSA), the U.S. Department of Veterans Affairs (VA), and private companies that participated in the initiative have moved to production use of DS4P. For example, a stakeholder who implemented the DS4P part 2 solution noted that the DS4P technical capability implemented in parts of Florida has saved some hospitals millions of dollars associated with the cost of care because the patients they treat with substance use issues or behavioral health issues were able to send an electronic referral and get a discharge performed earlier in the process.[116] Another technology stakeholder incorporated the DS4P technical functionality into its behavioral health and general hospital health IT solutions released this year. Most recently, SAMHSA developed an open source technology for patient consent management that uses the DS4P standard.[117] In September 2014, this technical solution was deployed into a live environment at a public health department.

The technical specifications are outlined in the HL7 Version 3 Implementation Guide: DS4P, Release 1

[108] *http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/.*

[109] *http://www.healthit.gov/sites/default/files/privacy-security/gwu-data-segmentation-final-cover-letter.pdf.*

[110] *http://www.healthit.gov/providers-professionals/patient-consent-electronic-health-information-exchange/health-information-privacy-law-policy.*

[111] For a policy discussion, see Substance Abuse and Mental Health Services Administration (SAMHSA)'s recent public listening session pertaining to the federal confidentiality of regulations: *https://www.federalregister.gov/articles/2014/05/12/2014-10913/confidentiality-of-alcohol-and-drug-abuse-patient-records.*

[112] *http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf.*

[113] *http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf.*

[114] *http://wiki.siframework.org/Data+Segmentation+for+Privacy+Use+Cases.*

[115] For more information about enabling privacy through data segmentation technology, see *http://www.healthit.gov/providers-professionals/enabling-privacy.*

[116] See Health IT Policy Committee's (HITPC) Privacy and Security Tiger Team Public Meeting, Transcript, (Apr. 16, 2014), p. 14, *http://www.healthit.gov/facas/sites/faca/files/PSTT_Transcript_Final_2014-04-16.pdf.*

[117] *http://www.healthit.gov/providers-professionals/ds4p-initiative.*

(DS4P IG), Part 1: CDA R2 and Privacy Metadata.[118] The DS4P IG describes the technical means of applying security labels (privacy metadata) which can be used to enact any security or privacy law, regulation, or policy so that the appropriate access control decisions will be made regarding downstream use, access or disclosure for specially protected data so that appropriate metadata tags are applied.

Conceptually, the DS4P approach utilizes metadata applied in layers (*e.g.* metadata applied to the header, section, or entry levels of a C–CDA document). The DS4P technical approach defaults to privacy metadata tagging at the document level. If an organization chooses to apply additional privacy metadata tagging within a document, that optional technical capability is also described within the IG for CDA. If a receiving system is unable to process section or entry level privacy metadata, the default is tagging at the document level. The approach relies on certain electronic actions being taken by both the sending system and the receiving system. The sending system must:

1. Identify information that requires enhanced protection or is subject to further restrictions;
2. Verify that the patient's privacy consent decision allows for the disclosure of health information; [119] and
3. Add privacy metadata to the health information being disclosed.

In turn, the receiving system must:

1. Be able to process the privacy metadata associated with the received health information; and
2. Verify the patient's consent before re-disclosure, if the receiving system has a need to re-disclose the information.

Data segmentation technology emerged to enable health care providers' use of technology to comply with existing privacy laws, regulations, and policies. The term ''data segmentation'' is often used to describe the electronic labeling or tagging of a patient's health information in a way that allows patients or providers to electronically share parts,[120] but not all, of a patient record. For example, data segmentation technology can be applied to the sharing of electronic sensitive health information, because that information is afforded greater protections under various state and federal laws,[121] as is discussed above. In this proposed rule, we propose to offer two certification criteria that would allow for health IT to be presented for testing and certification to the DS4P standard. We view the proposed offering of certification to these criteria as an initial step on technical standards towards the ability of an interoperable health care system to compute and persist the applicable permitted access, use or disclosure; whether regulated by state or federal laws regarding sensitive health information or by an individual's documented choices about downstream access to, or use or disclosure to others of, the identifiable individual's health information. The application of the DS4P standard at the document level is an initial step. We understand and acknowledge additional challenges surrounding the prevalence of unstructured data, sensitive images, and potential issues around use of sensitive health information by CDS systems. The adoption of document level data segmentation for structured documents will not solve these issues, but will help move technology in the direction where these issues can be addressed.

For example, today, electronic sensitive health information is not typically kept in the same repository as non-sensitive data. If security labels were applied to C–CDA documents at the time they are created (see ''data segmentation for privacy—send'' certification criterion), the receiving system would have more choices about how to store and use that sensitive information. If the receiving system had the capability to grant access to the tagged documents by using the security labels as part of the access control decision, then co-mingling the tagged, sensitive health information with the non-sensitive data becomes more achievable.

In July 2014, the HITPC provided recommendations on the use of DS4P technology to enable the electronic implementation and management of disclosure policies that originate from the patient, the law, or an organization, in an interoperable manner, so that electronic sensitive health information may be appropriately shared.[122] The HITPC noted a clear need to provide coordinated care for individuals with mental health and/or behavioral health issues. The HITPC recognized that the ability of patients to withhold consent to disclose information remains a concern for providers. In particular, providers want to provide the best care for patients, but they have concerns about incomplete records due to both professional obligation and liability considerations. While the need for providers to act on incomplete information is not necessarily new, the use of health IT may create an expectation of more complete information.[123] In recognition of the consumer, business, clinical, and technical complexities, the HITPC suggested a framework of two glide paths for the exchange of 42 CFR part 2-protected data, based on whether the subject is sending or receiving information.[124] As a first step in the glide path, the HITPC recommended that we include Level 1 (document level tagging) send and receive functionality.[125] Document level is the most basic level of privacy metadata tagging described in the DS4P standard. The following two proposals would implement the HITPC's recommendations.

• *Data Segmentation for Privacy—Send*

2015 Edition Health IT Certification Criterion
§ 170.315(b)(7) (Data segmentation for privacy—send)

A provider currently cannot send sensitive patient information electronically without some technical capability to indicate information is subject to restrictions, such as a prohibition on re-disclosure without consent, consistent with 42 CFR part 2. The sending provider also must have confidence that the receiver can properly handle electronically sent 42 CFR part 2-covered data. Because neither of these functionalities are currently supported in certification, sensitive health information such as 42 CFR part 2-covered data is often only

[118] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=354.* Completed Normative Ballot in January 2014 and was successfully reconciled in February 2014. HL7 approved the final standard for publication and ANSI approved in May 2014.

[119] *http://www.healthit.gov/providers-professionals/patient-consent-electronic-health-information-exchange.*

[120] The HL7 approved standard does allow for tagging at the data element level, but this proposed rule is suggesting just applying the DS4P to the document level.

[121] *http://www.healthit.gov/providers-professionals/patient-consent-electronic-health-information-exchange/health-information-privacy-law-policy.*

[122] See Health IT Policy Committee (HITPC) Recommendation Letter to ONC, July 2014, *http://www.healthit.gov/facas/sites/faca/files/PSTT_DS4P_Transmittal%20Letter_2014-07-03.pdf;* see also HITPC's Privacy and Security Tiger Team Public Meeting, Transcript, May 12, 2014, *http://www.healthit.gov/facas/sites/faca/files/PSTT_Transcript_Final_2014-05-12.pdf;* Public Meeting, Transcript, May 27, 2014, *http://www.healthit.gov/facas/sites/faca/files/PSTT_Transcript_Final_2014-05-27.pdf.*

[123] Id.

[124] For more details on the two glide paths for part 2-protected data, see *http://www.healthit.gov/facas/sites/faca/files/PSTT_DS4P_Transmittal%20Letter_2014-07-03.pdf.*

[125] Id. See also, related HITPC recommendations pertaining to data segmentation submitted to ONC in September 2010: *http://www.healthit.gov/sites/faca/files/hitpc_transmittal_p_s_tt_9_1_10_0.pdf.*

shared via paper and fax. We propose, consistent with the HITPC recommendations, that for certification to this criterion, a Health IT Module must be able to send documents using document level tagging (Level 1) in accordance with the DS4P IG. Document level tagging enables health IT to send the 42 CFR part 2-covered data along with the appropriate privacy metadata tagging and keep it sequestered from other data. The DS4P IG, which includes Level 1 functionality, provides guidance to allow, with proper authorization, a system to send a C–CDA with tags indicating any restrictions (such as a prohibition on re-disclosure without consent). While the DS4P IG specifies the technical means for applying privacy metadata tagging to C–CDA documents, it also optionally supports use of privacy metadata tagging within the document (at the section and entry levels). We only propose to require the document level functionality for sending as part of certification to this criterion.

• *Data Segmentation for Privacy—Receive*

2015 Edition Health IT Certification Criterion
§ 170.315(b)(8) (Data segmentation for privacy—receive)

In general, 42 CFR part 2-covered data is not currently provided electronically to healthcare providers through electronic exchange. Instead, the status quo remains to share 42 CFR part 2-covered data via paper and fax. In line with the HITPC recommendations, we propose a certification criterion that would require a Health IT Module to be able to receive 42 CFR part 2-covered data in accordance with the DS4P IG. DS4P at the document level (Level 1) of the recommendations allows recipient health IT to receive, recognize, and view documents with privacy metadata tagging indicating certain restrictions from 42 CFR part 2 providers with the document sequestered from other health IT data. A recipient provider could use document level tagging to sequester the document from other documents received and help prevent unauthorized re-disclosure, while allowing the sensitive data to flow more freely to authorized recipients. Thus, consistent with the HITPC recommendations, we propose that a Health IT Module be able to receive documents tagged with privacy metadata tagging (Level 1).

• *Care Plan*

2015 Edition Health IT Certification Criterion
§ 170.315(b)(9) (Care plan)

We propose to adopt a new 2015 Edition certification criterion that would reflect a Health IT Module's ability to enable a user to record, change, access, create and receive care plan information in accordance with the ''Care Plan document template'' in the C–CDA Release 2.0 standard.

The S&I Framework Longitudinal Coordination of Care (LCC) Longitudinal Care Plan Sub-Work Group defined a ''care plan'' as ''the synthesis and reconciliation of the multiple plans of care produced by each provider to address specific health concerns. It serves as the blueprint shared by all participants to guide the individual's care. As such, it provides the structure required to coordinate care across multiple sites, providers, and episodes of care.'' [126] The care plan helps multiple providers and caregivers align and coordinate care, which is especially valuable for patients living with chronic conditions and/or disabilities. It also provides a structure to promote the consideration of a patient's future goals and expectations in addition to managing their currently active health issues.

The C–CDA Release 2.0 contains a Care Plan document template that reflects these principles and provides a structured format for documenting information such as the goals, health concerns, health status evaluations and outcomes, and interventions. Note that the Care Plan document template is distinct from the ''Plan of Care Section'' in previous versions of the C–CDA. The Care Plan document template represents the synthesis of multiple plans of care (for treatment) for a patient, whereas the Plan of Care Section represented one provider's plan of care (for treatment). To make this distinction clear, the C–CDA Release 2.0 has renamed the previous ''Plan of Care Section'' as the ''Plan of Treatment Section (V2).''

Given the value for improved coordination of care, we propose a new 2015 Edition certification criterion for ''care plan'' that would require a Health IT Module to enable a user to record, change, access, create, and receive care plan information in accordance with the ''Care Plan document template'' in the HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes.[127] The IG provides guidance for implementing CDA documents, including the Care Plan document template. The ''transitions of care'' certification criterion proposed elsewhere in this section of the preamble would require a Health IT Module enable a user to send and receive transitions of care/referral summaries according to the C–CDA Release 2.0, which would include the Care Plan document template. Therefore, this criterion would focus only on a Health IT Module's ability to enable a user to record, change, access, create, and receive care plan information. We welcome comment on our proposal, including whether we should require certain ''Sections'' that are currently deemed optional as part of the Care Plan document template for certification to this criterion. For example, we invite comment on whether we should require the optional ''Health Status Evaluations and Outcomes Section'' and ''Interventions Section (V2)'' as part of certification to this criterion, and if so, for what value/use case.

• *Clinical Quality Measures—Record and Export*

2015 Edition Health IT Certification Criterion
§ 170.315(c)(1) (Clinical quality measures—record and export)

We propose to adopt a 2015 Edition certification criterion for ''clinical quality measures (CQM)—record and export'' that is revised in comparison to the 2014 Edition ''CQM—capture and export'' certification criterion (§ 170.314(c)(1)). In order to align with our use of the term ''record'' used in other 2014 and 2015 Edition certification criteria, we propose to call this certification criterion ''CQM—record and export.'' We explain the term ''record'' in the 2014 Edition final rule at 77 FR 54168.[128] We propose to require that a system user be able to export CQM data at any time the user chooses and without subsequent developer assistance to operate. We also propose to require that this certification criterion be part of the set of criteria necessary to satisfy the ''2015 Edition Base EHR'' definition (see also section III.B.1 of this preamble for a discussion of the proposed 2015 Edition Base EHR definition). Last, we solicit comment on the version of standards we should adopt for this certification criterion.

Standards for Clinical Quality Measures

In the 2014 Edition ''CQM—capture and export'' certification criterion, we require that technology must be able to export a data file formatted in

[126] *http://wiki.siframework.org/file/view/Care%20Plan%20Glossary_v25.doc/404538528/Care%20Plan%20Glossary_v25.doc.*

[127] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=379.*

[128] ''Record'' is used to mean the ability to capture and store information in technology.

accordance with the HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture (QRDA), DSTU Release 2 (July 2012) standard. We understand that the industry is working to harmonize both clinical quality measurement and CDS standards through initiatives such as the Clinical Quality Framework (CQF) S&I initiative. CDS guides a clinician to follow a standard plan of care, while CQMs measure adherence to a standard plan of care. Thus, these two areas are closely related and would benefit from standard ways to reference patient data within health IT as well as common logic to define a sub-population. The CQF S&I initiative is working to define a shared format, terminology, and logic between CQMs and CDS for improved efficiency, cost, and quality of care.

In order to harmonize CQM and CDS standards, the industry is using pieces of existing CQM standards (*e.g.,* Health Quality Measures Format (HQMF), QRDA Categories I and III, and the Quality Data Model (QDM)) and CDS standards (*e.g.,* Clinical Decision Support Knowledge Artifact Specification (also known as HeD Schema) and the Virtual Medical Record). HL7 issued an errata (September 2014) [129] that reflects updates based on an incremental version of the harmonized CQM and CDS standards (*i.e.,* QDM-based HQMF Release 2.1).[130] This errata is meant to be used in conjunction with the July 2012 QRDA IG we adopted in the 2014 Edition. Our understanding is that the fully harmonized CQM and CDS standards will be based on the Quality Improvement and Clinical Knowledge (QUICK) data model,[131] and that the industry expects to ballot a QUICK FHIR-based DSTU serving the same function as the HQMF standard at the May 2015 HL7 meeting. Subsequent standards for electronically processing and reporting CQMs and CDS would then be expected to be built on the QUICK data model, including a QRDA-like standard based on the anticipated QUICK FHIR-based DSTU.

Given the timing of this proposed rule and the expected deliverables for harmonized CQM and CDS standards as described above, we solicit comment on the version of QRDA or the QRDA-like standards we should adopt for this certification criterion. Specifically, we solicit comment on the following three options:

- HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture (QRDA), DSTU Release 2 (July 2012);
- HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture (QRDA), DSTU Release 2 (July 2012) and the September 2014 Errata; or
- A QRDA-like standard based on the anticipated QUICK FHIR-based DSTU.CQM standards we should adopt for this certification criterion.

We anticipate that the QUICK data model will not be available to review during the public comment period of this NPRM, and welcome stakeholder input on the usefulness of adopting the current (July 2012) QRDA standard alone or in conjunction with the September 2014 errata given that we anticipate there will be harmonized CQM and CDS standards available in mid-2015. We also seek to understand the tradeoffs stakeholders perceive in adopting each standard provided that the EHR Incentive Programs Stage 3 proposed rule is proposing that technology certified to the 2015 Edition would not be required until January 1, 2018, but that technology certified to the 2015 Edition ''CQM—record and export'' certification criterion would be needed for EPs, eligible hospitals, and CAHs participating in the EHR Incentive Programs Stage 3 objectives and measures in 2017. Thus, we welcome input on recommended QRDA standards for the ''CQM—record and export'' certification criterion factoring in where the industry may be with adoption of CQM and CDS standards over the next few years.

User Ability To Export CQM Data

We have received stakeholder feedback that some systems certified to the 2014 Edition ''CQM—capture and export'' certification criterion do not provide users with the ability to export data ''on demand'' nor to export batches of multiple patients simultaneously. Rather, some users of certified health IT must request this functionality from the health IT developer. Our intent is that users should be able to export CQM data formatted to the QRDA standard at any time the user chooses for one or multiple patients and without additional assistance. Thus, as proposed, when a Health IT Module is presented for certification to this criterion, we would expect that testing of the Health IT Module would include demonstration of a user's ability to export CQM data without subsequent health IT developer assistance beyond normal orientation/training.

- *Clinical Quality Measures—Import and Calculate*

2015 Edition Health IT Certification Criteria
§ 170.315(c)(2) (Clinical quality measures—import and calculate)

We propose to adopt a 2015 Edition certification criterion for ''clinical quality measures (CQM)—import and calculate'' that is revised in comparison to the 2014 Edition ''CQM—import and calculate'' certification criterion (§ 170.314(c)(2)). We propose to require that a system user be able to import CQM data at any time the user chooses and without subsequent health IT developer assistance to operate. We also no longer include an exemption that would allow a Health IT Module presented for certification to all three CQM certification criteria (§§ 170.315(c)(1), (c)(2), and (c)(3)) to not have to demonstrate the data import capability. Last, we solicit comment on our intended direction for testing and certifying health IT and the version of standards we should adopt for this certification criterion.

User Ability To Import CQM Data

We have received stakeholder feedback that some systems certified to the 2014 Edition ''CQM—import and calculate'' certification criterion do not provide users the ability to import data ''on demand,'' and rather users must request this functionality from the system developer or vendor. Our intent is that users should be able to import CQM data formatted to the QRDA standard for one or multiple patients at any time the user chooses and without additional assistance. Thus, when a Health IT Module is presented for certification to this criterion, we would expect that testing of the Health IT Module would include demonstration of a user's ability to import CQM data without subsequent health IT developer assistance beyond normal orientation/training.

Import of CQM Data

For the 2014 Edition, we do not require systems that certify to § 170.314(c)(1) (CQM—capture and export), § 170.314(c)(2) (CQM—import and calculate), and § 170.314(c)(3) (CQM—electronic submission) to have to demonstrate that they can import data files in accordance with the QRDA

[129] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35.* Please note that in order to access the errata, the user should download the ''HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture—Category I, DSTU Release 2 (US Realm)'' package.

[130] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=97.*

[131] *http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=1045.*

standard. In 2012, we adopted this policy because we did not believe that systems that could perform capture, export, and electronic submission functions would need to import CQM data as they were in essence ''self-contained'' (77 FR 54231). However, we have received stakeholder input recommending that all systems should be able to import CQM data and that there could be instances were a provider using one technology to record CQM data could not subsequently import such data into a different technology. We agree with this feedback. Therefore, this exemption will no longer carry forward as part of the proposed 2015 Edition version of this certification criterion. This means that a Health IT Module presented for certification to this certification criterion (§ 170.315(c)(2)) would need to be able to demonstrate the ability to import data in order to be certified to this certification criterion even if they also certify to provide ''record and export'' and ''electronic submission/report'' functions.

Testing of Import and Calculate Functionalities

The testing procedures for the 2014 Edition ''CQM—import and calculate'' certification criterion only test that technology can import a small number of test records and use those for calculation of CQM results. We have received feedback that technology should be able to import a larger number of test records and that we should test this ability to reflect real-world needs for technology. With the import of a large number of records, technology also needs to be able to de-duplicate records for accurate calculation of CQM results. Therefore for testing and certification to the proposed 2015 Edition ''CQM—import and calculate'' certification criterion, we intend for testing to include that technology can import a larger number of test records compared to testing for the 2014 Edition and automatically de-duplicate them for accurate CQM calculation. We welcome comment on our proposed intentions to test a larger number of test records compared to the 2014 Edition test procedure and that a Health IT Module could eliminate duplicate records. We also request comment on the number of test records we should consider testing a Health IT Module for performing import and calculate functions.

Standards for Clinical Quality Measures

We describe above in the preamble for the proposed 2015 Edition ''CQM—record and export'' certification criterion our understanding of the industry's timeline and expected deliverables for harmonized CQM and CDS standards. Given the discussion above, we also solicit comment on the QRDA standards we should consider adopting for this 2015 Edition ''CQM—import and calculate'' certification criterion.

- *Clinical Quality Measures—Report*

2015 Edition Health IT Certification Criteria
§ 170.315(c)(3) [Reserved]

In the 2014 Edition, we adopted a ''CQM—electronic submission'' certification criterion that requires technology to enable a user to electronically create a data file for transmission of CQM data in accordance with QRDA Category I and III standards and ''that can be electronically accepted by CMS'' (§ 170.314(c)(3)). We have received stakeholder feedback recommending we better align our certification policy and standards for electronically-specified CQM (eCQM) reporting with other CMS programs that include eCQMs, such as the Physician Quality Reporting System (PQRS) and Hospital Inpatient Quality Reporting (IQR) programs. The PQRS and Hospital IQR programs update their measure specifications on an annual basis through rulemaking in the Physician Fee Schedule (PFS) and Inpatient Prospective Payment Systems (IPPS) rules respectively.

To better align with the reporting requirements of other CMS programs, we intend to propose certification policy for reporting of CQMs in or with annual PQRS and/or Hospital IQR program rulemaking. We anticipate we will propose standards for reporting of CQMs that reflect CMS' requirements for the ''form and manner'' of CQM reporting (*e.g.,* CMS program-specific QRDA standards), allowing for annual updates of these requirements as necessary. Under this approach, the ''CQM—report'' certification policy and associated standards for the 2015 Edition that support achieving EHR Incentive Program requirements would be proposed jointly with the calendar year (CY) 2016 PFS and/or IPPS proposed rules. We anticipate these proposed and final rules will be published in CY 2015. We clarify that we anticipate removing ''electronic'' from the name of this certification criterion. As described in the preamble, we expect that all functions proposed in the 2015 Edition certification criteria are performed or demonstrated electronically. Thus, it is not necessary to specifically include this requirement in the title of this certification criterion. We also anticipate naming this certification criterion ''report'' instead of ''submission'' to better align with the language we use in other certification criteria that also require demonstration of the same functionality to submit data.

- *Clinical Quality Measures—Filter*

2015 Edition Health IT Certification Criterion
§ 170.315(c)(4) (Clinical quality measures—filter)

We propose to adopt a new 2015 Edition certification criterion for CQM filtering. In the Voluntary Edition proposed rule, we proposed a new certification criterion that would require health IT to be able to record structured data for the purposes of being able to filter CQM results to create different patient population groupings by one or more of a combination of certain patient characteristics [132] (79 FR 10903–04). We proposed this capability to support eCQM reporting where the reporting entity is not an individual provider but rather a group practice or an accountable care organization (ACO). We also proposed certain patient characteristics that would support identification of health disparities, help providers identify gaps in quality, and support a provider in delivering more effective care to sub-groups of their patients. We did not adopt this certification criterion in the 2014 Edition Release 2 final rule as we received comments recommending we further refine the use cases and perform more analysis of which data elements are being captured in standardized ways (79 FR 54462).

CMS offers various options for providers to report quality data as part of a group instead of individually reporting as individual providers. For example, the PQRS offers the Group Practice Reporting Option (GPRO) that allows for assessment and payment (or adjustment) based on reporting of data on quality measures at the group level. Similarly, there are group reporting options, including the GRPO under the PQRS for reporting data used to assess quality for purposes of the Value Modifier under the Medicare Physician Fee Schedule. Another CMS group reporting option is the Comprehensive Primary Care (CPC) initiative. In the CPC initiative, participating primary

[132] Practice site and address; Tax Identification Number (TIN), National Provider Identifier (NPI), and TIN/NPI combination; diagnosis; primary and secondary health insurance, including identification of Medicare and Medicaid dual eligible; demographics including age, sex, preferred language, education level, and socioeconomic status.

care practices receive care management fees to support enhanced, coordinated services. In the CPC initiative, each physical site location is counted as a ''practice.'' A group practice may encompass several primary care sites, of which some, but not all, are participating in CPC. Because the unit of analysis in CPC is the practice site, CMS requires all CPC participants to report CQMs at the level of the practice rather than at the level of the individual provider. Each CPC practice's quality results, which include performance on patient experience and claims measures as well as CQMs, are tied to the distribution of any Medicare shared savings calculated and earned at the level of the Medicare population of each region participating in the initiative.

ACO models and programs, such as the Medicare Shared Savings Program (MSSP) and CMS Pioneer ACO Model, include groups of doctors, hospitals, and other health care providers who come together voluntarily to give coordinated high quality care to their patients. In ACO models and programs, the providers that participate in the ACO share responsibility for the care and outcomes of their patients. For example, MSSP participants are rewarded if the ACO lowers the growth in its health care costs while meeting performance standards on quality of care. ACOs are required to internally report on cost and quality metrics associated with the activities of their practitioners, to promote the use of evidence-based medicine, and to support the care coordination activities of their practitioners. Understanding the practice patterns of individual practitioners for services provided on behalf of the ACO is therefore important for such organizations.

In some cases, not all providers practicing at a particular practice site location or in an ACO will be participating in the group practice or ACO reporting options. The National Provider Identifier (NPI) is insufficient by itself to attribute a provider's performance to a particular group practice or ACO, as the provider could practice in multiple health care organizations. Likewise, a health care organization may have multiple Tax Identification Numbers (TINs). Currently, data may be accessed by filtering on either the TIN or the NPI, but not in combination due, in part, to current CMS reporting requirements and limitations of health IT being used by providers. The ability to filter by a combination of NPI/TIN could allow for more specific and proper attribution of a provider's performance to the correct organization for aggregating group practice or ACO quality measure results.

Health IT should support an organization's ability to filter both individual patient level and aggregate level eCQM results by data that would support administrative reporting as well as identification of health disparities and gaps in care for patients being treated at particular group practice sites or in a given ACO. We, therefore, propose a new certification criterion for CQM filtering that would require health IT to be able to record data (according to specified standards, where applicable) and filter CQM results at both patient and aggregate levels by each one and any combination of the following data:

- TIN;
- NPI;
- Provider type;
- Patient insurance;
- Patient age;
- Patient sex in accordance with the standard specified in § 170.207(n)(1) (HL7 Version 3);
- Patient race and ethnicity in accordance with the standards specified in § 170.207(f)(1) (OMB standard) and, at a minimum, (f)(2) (''Race & Ethnicity—CDC'' code system in the PHIN VADS);
- Patient problem list data in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4) (September 2014 Release of the U.S. Edition of SNOMED CT®); and
- Practice site address.

We clarify that a Health IT Module must be able to filter by any combination of the proposed data elements (*i.e.,* by any one (*e.g.,* provider type) or a combination of any of the data elements (*e.g.,* combination of TIN and NPI or combination of all data)). We also note that this combination requirement is different than other proposed certification criteria in that it requires all combinations to be demonstrated for certification and not just one. We anticipate that if adopted, stakeholders may want to expand the list of data in this certification criterion and support the reporting needs of additional programs over time. Our intent with this proposal is to continue to work with CMS and other stakeholders to ensure that this list of data represents a common and relatively stable set across program needs in support of program alignment.

For certain data elements, we have specified vocabulary standards (as identified above) to maintain consistency in the use of adopted national standards. As part of the 2014 Edition, technology is certified to record patient race, ethnicity, and problem lists in accordance with standards. In this proposed rule, for the ''demographics'' certification criterion and other criteria, we propose to certify a Health IT Module to record patient sex, race, and ethnicity in accordance with standards we propose to adopt as part of the 2015 Edition. We also propose to certify a Health IT Module to the record patient problem lists in accordance with the latest version of the SNOMED CT® standard. Please refer to the proposed ''demographics'' and ''problem list'' certification criteria discussed earlier in this section of the preamble for a more detailed discussion about the standards. We are also aware that patient sex, race, and ethnicity are being collected as supplemental data to the Quality Reporting Data Architecture (QRDA) Category I and III files for eCQM reporting to CMS. Collection of patient date of birth is currently required as part of the 2014 Edition ''demographics'' certification criterion, and is being proposed for the 2015 Edition ''demographics'' certification criterion. Therefore, we believe there should not be a large developmental burden to enable a Health IT Module to record these data because they are already being collected through policy established in the 2014 Edition and/or are being proposed as part of 2015 Edition certification criteria discussed elsewhere in this proposed rule.

We are aware that patient insurance can be collected using a payer value set that denotes whether the patient has Medicare, Medicaid, and/or another commercial insurance. We solicit comment on other payer value sets that could be leveraged to support this proposal. We believe that provider type could also inform quality improvement if there are differences in quality measure results by different types of providers. We are aware of the Healthcare Provider Taxonomy Code Set designed to categorize the type, classification, and/or specialization of health care providers.[133] Health care providers applying for an NPI must select a Healthcare Provider Taxonomy Code or code description during the application process. We solicit comment on the appropriateness of this code set for classifying provider types as well as other standards that could be used classify provider types.

In order to support the identification of CQM results for a particular practice, we propose to include practice site address in the list of data. We note that

[133] *http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Taxonomy.html*

while this information may not be needed for CQM filtering at the ACO level, certification would require that health IT enables a user to record practice site address, but not dictate that a user must include this information. We believe the industry is aware of the need to identify a standard way to represent address. While such a standard is being developed, we believe that to support group or practice reporting, having the address is one of the key data elements that would allow a provider using health IT to filter CQM results at the practice or group level. We solicit comment on standards for collecting address data that could be leveraged to support this functionality.

We solicit comment on the appropriateness of the proposed data elements for CQM filtering, including whether they are being captured in standardized vocabularies. We also solicit comment on additional data elements that we should consider for inclusion and standardized vocabularies that might be leveraged for recording this information in health IT.

• *Authentication, Access Control, and Authorization*

2015 Edition Health IT Certification Criterion
§ 170.315(d)(1) (Authentication, access control, and authorization)

We propose to adopt a 2015 Edition ''authentication, access control, and authorization'' certification criterion that is unchanged in comparison to the 2014 Edition ''authentication, access control, and authorization'' criterion (§ 170.314(d)(1)).

• *Auditable Events and Tamper-Resistance*

2015 Edition Health IT Certification Criterion
§ 170.315(d)(2) (Auditable events and tamper-resistance)

We propose to adopt a 2015 Edition ''auditable events and tamper-resistance'' certification criterion that is unchanged in comparison to the 2014 Edition ''auditable events and tamper-resistance'' criterion (§ 170.314(d)(2)). We seek comment, however, on two issues. In August 2014, the HHS Office of Inspector General (OIG) released a report entitled ''The Office of the National Coordinator for Health Information Technology's Oversight of the Testing and Certification of Electronic Health Records.'' [134] In that report, the OIG found that ONC approved test procedures did not address common security issues, including ''logging emergency access or user privilege changes.'' The OIG therefore recommended ''. . . that ONC work with NIST to strengthen EHR test procedure requirements so that the ATCBs [ONC-Authorized Testing and Certification Bodies] can ensure that EHR vendors incorporate common security and privacy features into the development of EHRs.'' [135]

The standards adopted at § 170.210(e) and referenced by the 2014 Edition ''auditable events and tamper-resistance'' and ''audit report(s)'' certification criteria require that technology must be able to record audit log information as specified in sections 7.2 through 7.4, 7.6 and 7.7 of the standard adopted at 45 CFR 170.210(h). The standard adopted at § 170.210(h) is ASTM E2147.[136] Section 7.6 of ASTM E2147 specifies that audit log content needs to include the ''type of action'' and references six ''actions:'' Additions, deletions, change, queries, print, and copy. Section 7.7 requires that the audit log record when patient data is accessed. So while not explicitly referenced in section 7.6, the action of ''access'' or viewing of a patient's information is also required to be recorded for certification. Moreover, we clarify that an ''emergency access'' event is expected to be recorded (just like any other access) in accordance with section 7.7.

Because it does not appear that the ASTM standard indicates recording an event when an individual's user privileges are changed, we seek comment on whether we need to explicitly modify/add to the overall auditing standard adopted at 170.210(e) to require such information to be audited or if this type of event is already audited at the point of authentication (*e.g.,* when a user switches to a role with increased privileges and authenticates themselves to the system). We also seek comments on any recommended standards to be used in order to record those additional data elements.

In a 2013 report entitled ''Not All Recommended Safeguards Have Been Implemented in Hospital EHR Technology (OEI–01–11–00570),'' [137] the OIG recommended that ONC should propose a revision to this certification criterion to require that EHR technology keep the audit log operational whenever the EHR technology is available for updates or viewing or, alternatively, CMS could update its meaningful use criteria to require providers to keep the audit log operational whenever EHR technology is available for updates or viewing.[138] As a result of that report, in the Voluntary Edition proposed rule, we proposed an ''auditable events and tamper resistance'' certification criterion that would have required technology to prevent all users from being able to disable an audit log. While several commenters supported the proposal, an equal share expressed concern, including the HITSC. The HITSC recommended against implementing this proposal, indicating that the requirements of the 2014 Edition certification criterion (identifying only a limited set of users that could disable the audit log and logging when and by whom an audit log was disabled and enabled) provided sufficient parameters to determine the accountable party in the event of a security incident.[139] Other commenters contended that including an absolute prohibition would be problematic because there are valid and important reasons for users to disable the audit log, including allowing a system administrator to disable the audit log for performance fixes, stability, disaster recovery, and system updates or allowing a system administrator to disable it when there is rapid server space loss which is hindering a provider from accessing needed clinical information in a timely manner.

We reiterate our policy first espoused with the adoption of the 2014 Edition ''auditable events and tamper resistance'' certification criterion in that the ability to disable the audit log must be restricted to a limited set of users to meet this criterion. The purpose of this certification criterion is to require health IT to demonstrate through testing and certification that it has certain security capabilities built in. As we have evaluated both OIG's input and that of commenters, we believe our certification criterion is appropriately framed within the parameters of what our regulation can reasonably impose as a condition of certification. This regulation applies to health IT and not to the people who use it. Thus, how an individual provider or entity chooses to ultimately implement health IT that has been certified to this or any other certification criterion does so outside the scope of this regulation.

[134] *http://oig.hhs.gov/oas/reports/region6/61100063.pdf*

[135] *http://oig.hhs.gov/oas/reports/region6/61100063.pdf*

[136] *http://www.astm.org/Standards/E2147.htm.* The standard is also incorporated by reference at 45 CFR 170.299(c)(1) and available at the Office of the Federal Register.

[137] *https://oig.hhs.gov/oei/reports/oei-01-11-00570.pdf.*

[138] *https://oig.hhs.gov/oei/reports/oei-01-11-00570.pdf.*

[139] *http://www.healthit.gov/FACAS/sites/faca/files/Baker_PSWG_2015editionnprm_public_comment_V2.pdf.*

We also received feedback to the Voluntary Edition proposed rule that there may be some events recorded in the audit log that may be more critical to record than other events. Commenters noted that there may be a critical subset of events that should remain enabled at all times, while other events could be turned off during critical times or for system updates by a subset of users. As noted above, the standards adopted at § 170.210(e) and referenced by the 2014 Edition ''auditable events and tamper-resistance'' certification criterion requires that health IT technology must be able to record additions, deletions, changes, queries, print, copy, access. The 2014 Edition also required the log to record when the audit log is disabled and by whom and that such capability must be restricted to a limited set of identified users. As a result, we again seek comment on whether:

- There is any alternative approach that we could or should consider;
- There is a critical subset of those auditable events that we should require remain enabled at all times, and if so, additional information regarding which events should be considered critical and why; and
- Any negative consequences may arise from keeping a subset of audit log functionality enabled at all times.
- *Audit Report(s)*

2015 Edition Health IT Certification Criterion
§ 170.315(d)(3) (Audit report(s))

We propose to adopt a 2015 Edition ''audit reports(s)'' certification criterion that is unchanged in comparison to the 2014 Edition ''audit reports(s)'' criterion (§ 170.314(d)(3)).

- *Amendments*

2015 Edition Health IT Certification Criterion
§ 170.315(d)(4) (Amendments)

We propose to adopt a 2015 Edition ''amendments'' certification criterion that is unchanged in comparison to the 2014 Edition ''amendments'' criterion (§ 170.314(d)(4)). We note that this certification criterion only partially addresses the amendment of protected health information (PHI) requirements of 45 CFR 164.526.

- *Automatic Access Time-Out*

2015 Edition Health IT Certification Criterion
§ 170.315(d)(5) (Automatic access time-out)

We propose to adopt a 2015 Edition ''automatic access time-out'' certification criterion that is unchanged (for the purposes of gap certification) in comparison to the 2014 Edition ''automatic log-off'' criterion (§ 170.314(d)(5)). The 2014 Edition ''automatic log-off'' criterion requires a Health IT Module to ''prevent a user from gaining further access to an electronic session after a predetermined time of inactivity.'' In June 2014, the Privacy and Security Workgroup (PSWG) of the HITSC assessed the automatic log-off criterion.[140] While the 2014 Edition criterion refers to ''sessions,'' the PSWG noted the need to recognize that many systems are not session-based. Instead, systems may be stateless, clientless, and/or run on any device. The PSWG further noted that the risk that this criterion addresses is the potential that protected health information could be disclosed through an unattended device. The HITSC recommended that this certification criterion should not be overly prescriptive so as to inhibit system architecture flexibility.

To clarify this intent and eliminate the reference to ''session,'' the PSWG suggested to the HITSC that this criterion by refined to state ''automatically block access to protected health information after a predetermined period of inactivity through appropriate means until the original user re-authenticates or another authorized user authenticates.'' We agree in substance with the PSWG work and HITSC recommendations. Accordingly, we propose a 2015 Edition ''automatic access time-out'' certification criterion that reflects the HITSC recommendations and the work of the PSWG. Specifically, the criterion would require a Health IT Module to demonstrate that it can automatically stop user access to health information after a predetermined period of inactivity and require user authentication in order to resume or regain the access that was stopped. We note, however, that we do not believe this would have any impact on testing and certification as compared to testing and certification to the 2014 Edition ''automatic log-off'' criterion (*i.e.,* the 2015 ''automatic access time-out'' criterion would be eligible for gap certification). We welcome comments on this assessment.

- *Emergency Access*

2015 Edition Health IT Certification Criterion
§ 170.315(d)(6) (Emergency access)

We propose to adopt a 2015 Edition ''emergency access'' certification criterion that is unchanged in comparison to the 2014 Edition ''emergency access'' criterion (§ 170.314(d)(6)).

- *End-User Device Encryption*

2015 Edition Health IT Certification Criterion
§ 170.315(d)(7) (End-user device encryption)

We propose to adopt a 2015 Edition ''end-user device encryption'' certification criterion that is unchanged (for the purposes of gap certification) in comparison to the 2014 Edition ''end-user device encryption'' criterion (§ 170.314(d)(7)). We propose to require certification to this criterion consistent with the most recent version of Annex A: Approved Security Functions (Draft, October 8, 2014) for Federal Information Processing Standards (FIPS) Publication 140–2.[141] The purpose of this document is to provide a list of the approved security functions applicable to FIPS PUB 140–2. To maintain and update our certification requirements to the most recent NIST-approved security functions, we propose to move to the updated version of Annex A (Draft, October 8, 2014). We proposed to adopted this updated version of Annex A at § 170.210(a)(3). We note, however, that we do not believe that this would have any impact on testing and certification as compared to testing and certification to the 2014 Edition ''end-user device encryption'' criterion (*i.e.,* the 2015 ''end-user device encryption'' criterion would be eligible for gap certification). We welcome comments on this assessment.

- *Integrity*

2015 Edition Health IT Certification Criterion
§ 170.315(d)(8) (Integrity)

We propose to adopt a 2015 Edition ''integrity'' certification criterion that is unchanged in comparison to the 2014 Edition ''integrity'' criterion (§ 170.314(d)(8)). However, we propose a change in how a Health IT Module would be tested and certified to this criterion. The 2011 and 2014 editions of this criterion have been available for individual testing and certification. We propose that the 2015 Edition ''integrity'' criterion would be tested and certified to support the context for which it was adopted—upon receipt of a summary record in order to ensure the integrity of the information exchanged

[140] *http://www.healthit.gov/facas/sites/faca/files/HITSC_PSWG_2015NPRM_Update_2014-06-17.pdf.*

[141] *http://csrc.nist.gov/publications/fips/fips140-2/fips1402annexa.pdf.*

(see § 170.315(d)(8)(ii)). Therefore, we expect that this certification criterion would most frequently be paired with the ToC certification criterion for testing and certification.

In the 2014 Edition propose rule, we sought comment on whether we should leave the standard for the 2014 Edition ''integrity'' certification criterion as SHA–1 [142] or replace it with SHA–2,[143] as SHA–2 is a much stronger security requirement. In the 2014 Edition final rule (77 FR 54251), we determined that the SHA–1 standard should serve as a floor and technology could be certified to the 2014 Edition ''integrity'' certification criterion if it included hashing algorithms with security strengths *equal to or greater than* SHA–1. We also noted that the Direct Project specification requires that SHA–1 and SHA–256 (one type of SHA–2 hash algorithms) be supported, which still remains the case today.

It is our understanding that many companies, including Microsoft and Google, plan to sunset (deprecate) SHA–1 no later than January 1, 2017.[144] While the SHA–1 standard serves as the baseline standard for certification to the proposed 2015 Edition ''integrity'' certification criterion and health IT *could* be certified to a security strength greater than SHA–1 (*e.g.,* SHA–2), we seek comments on if, and when, we should set the baseline for certification to the 2015 Edition ''integrity'' certification criterion at SHA–2. For example, we could adopt and move to SHA–2 as the baseline certification requirement with the effective date of a subsequent file rule. This would likely be in late 2015 (considering the start of testing and certification), and consistent with the current trajectory of the industry in this area. Alternatively, we could set an effective date within the criterion for when the baseline for certification would shift from SHA–1 to SHA–2 (*e.g.,* beginning 2017).

• *Accounting of Disclosures*

2015 Edition Health IT Certification Criterion
§ 170.315(d)(9) (Accounting of disclosures)

We propose to adopt a 2015 Edition ''accounting of disclosures'' certification criterion that is unchanged in comparison to the 2014 Edition ''accounting of disclosures'' criterion (§ 170.314(d)(9)). We note that the 2015 Edition criterion is no longer designated ''optional'' because such a designation is no longer necessary given that we have discontinued the Complete EHR definition and Complete EHR certification beginning with the 2015 Edition health IT certification criteria.

• *View, Download, and Transmit to 3rd Party (VDT)*

2015 Edition Health IT Certification Criterion
§ 170.315(e)(1) (View, download, and transmit to 3rd party)

We propose to adopt a 2015 Edition ''VDT'' criterion that is revised in comparison to the 2014 Edition ''VDT'' criterion (§ 170.314(e)(1)).

Clarified Introductory Text for 2015 Edition VDT Certification Criterion

In the Voluntary Edition proposed rule, we proposed to make clarifying changes to the introductory text at § 170.315(e)(1) to make it clear that this health IT capability is patient-facing and for patients to use. Commenters generally supported clarifying the introductory text of VDT. Commenters stressed the importance of allowing authorized representatives the ability to perform the VDT functionality. However, due to our approach to only finalize a subset of modifications in the 2014 Edition Release 2 final rule, we chose not to make that revision in the 2014 Edition Release 2 final rule. Therefore, we again propose to revise the introductory text to lead with ''Patients (and their authorized representatives) must be able to use health IT to . . .'' We also propose to use this same phrase at the beginning of each specific capability for VDT to reinforce this point. We note that this proposed requirement included in this criterion *does not override* an individual's right to access protected health information (PHI) in a designated record set under 45 CFR 164.524.

Common Clinical Data Set, Updated C–CDA, and Diagnostic Image Reports

We propose to include an updated Common Clinical Data Set for the 2015 Edition that includes references to new and updated vocabulary standards code sets. Please also see the Common Clinical Data Set definition proposal in section III.B.3 of this preamble. For the same reasons discussed in the proposed 2015 Edition ToC certification criterion, we also propose to reference the updated version of the C–CDA (Draft Standard for Trial Use, Release 2.0) for this certification criterion; and note, for the reasons discussed under the 2015 ToC certification criterion, compliance with Release 2.0 cannot include the use of the ''unstructured document'' document-level template for certification to this criterion.

We also propose that a Health IT Module must demonstrate that it can make diagnostic image reports available to the patient in order to be certified. A diagnostic imaging report contains a consulting specialist's interpretation of image data. It is intended to convey the interpretation to the referring (ordering) physician, and becomes part of the patient's medical record. We believe it is important to include this information in a patient's record to improve care. Therefore, we propose to include diagnostic imaging reports in the certification criterion as something a Health IT Module must be able to make accessible to patients. Again, to prevent any misinterpretation, we reiterate for stakeholders that this proposed rule and proposed certification criterion apply to a Health IT Module with regard to what must be demonstrated for the Health IT Module to be certified and does not govern its use.

We request comment on whether we should require testing and certification for the availability of additional patient data through the view, download, transmit, and API (discussed below) capabilities. For example, should patient data on encounter diagnoses, cognitive status, functional status, or other information also be made available to patients (or their authorized representatives) through these capabilities? Additionally, similar to our proposals for the data portability certification criterion, we request comment on including requirements in this criterion to permit patients (or their authorized representatives) to select their health information for, as applicable, viewing, downloading, transmitting, or API based on a specific date or time (*e.g.,* on 10/24/2015), a period of time (*e.g.,* the last 3 years), or all the information available.

VDT—Application Access to Common Clinical Data Set

To complement the API capabilities in the proposed ''Application Access to Common Clinical Data Set'' criterion at § 170.315(g)(7), which are intended to be used by health IT purchasers in the context of providing application access to the Common Clinical Data Set, we also propose to require that the same capabilities be met as part of the 2015 Edition VDT certification criterion. While in some respects it could be argued that repeating these capabilities in the VDT certification criterion are duplicative, we believe the contexts under which the capabilities proposed by this criterion and proposed at

[142] *http://csrc.nist.gov/publications/fips/fips180-4/fips-180-4.pdf.*

[143] *http://csrc.nist.gov/publications/fips/fips180-4/fips-180-4.pdf.*

[144] *http://www.symantec.com/en/au/page.jsp?id=sha2-transition.*

§ 170.315(g)(7) would be used and the contexts under which certification to this criterion would be sought are distinct enough to warrant this repetition (*i.e.,* in some cases a health IT developer may seek certification solely to this criterion). In recognition of the fact that some health IT developers will choose to build a more tightly integrated system that could rely on the same underlying capabilities developed to meet § 170.315(g)(7), we clarify that health IT developers could provide the information necessary to satisfy the ''documentation'' and ''terms of use'' requirements in § 170.315(e)(1)(iii)(D) and (E) of this criterion and § 170.315(g)(7)(iv) and (v) only once so long as the information addresses any potential technical differences in the application access capabilities provided (*e.g.,* a RESTful web service for § 170.315(e)(1) versus a SOAP web service for § 170.315(g)(7)). As proposed as part of certification in conjunction with § 170.315(g)(7), we similarly propose for this criterion to require ONC–ACBs to submit a hyperlink (as part of a product certification submission to the CHPL) that would allow any interested party to access the API's documentation and terms of use. This hyperlink would first need to be provided by the health IT developer to the ONC–ACB.

Including these capabilities in the VDT certification criterion could address several aspects that currently pose challenges to individuals (and their families) accessing their health information (*e.g.,* multiple ''portals''). Additionally, we have coordinated with CMS to have the proposed meaningful use measure for VDT revised to allow for responses to data requests executed by the API functionality to count in the measure's numerator (please see the EHR Incentive Programs Stage 3 proposed rule published elsewhere in this issue of the **Federal Register**). This combination of technological capability and measurement flexibility could enhance an individual's ability to converge their data in the application of their choice. Furthermore, by including these capabilities in this criterion, we ensure that health IT developers who seek certification only to this criterion but not (g)(7) because of their market focus, will equally be required to include an API available as part of their technology.

We note that readers should also review the proposed ''API'' certification criterion in this section of the preamble for requests for comments that may impact the finalization of the API proposal included in this certification criterion. For example, we request public comment on what additional requirements might be needed to ensure the fostering of an open ecosystem around APIs so that patients can share their information with the tools, applications, and platforms of their own choosing.

Activity History Log

In the Voluntary Edition proposed rule, we proposed to include two new data elements for the activity history log: transmission status and addressee. Due to the approach we took with the 2014 Edition Release 2 final rule, we did not finalize either proposal. However, we received support for our proposal to include the addressee as a data element in the history log. Therefore, we propose to include ''addressee'' as a new data element in the 2015 Edition VDT criterion related to the activity history log. Although the 2014 Edition VDT criterion requires that the action of ''transmit'' be recorded, we did not specify that the intended destination be recorded. We believe this transactional history is important for patients to be able to access, especially if a patient actively transmits their health information to a 3rd party or another health care provider.

Patient Access to Laboratory Test Reports

In February 2014, CMS, the CDC, and the Office for Civil Rights (OCR) issued a final rule that addressed the interplay between the CLIA rules, state laws governing direct patient access to their laboratory test reports, and the HIPAA Privacy Rule.[145] The final rule permits laboratories to give a patient, a patient's ''personal representative,'' or a person designated by the patient, as applicable, access to the patient's completed test reports upon the patient's or patient's personal representative's request.[146] The final rule also eliminated the exception under the HIPAA Privacy Rule to an individual's right to access his or her protected health information when it is held by a CLIA-certified or CLIA-exempt laboratory. While patients can continue to get access to their laboratory test reports from their doctors, these changes give patients a new option to obtain their test reports directly from the laboratory while maintaining strong protections for patients' privacy.

We seek to ensure that the test reports that are delivered by providers to patients through the VDT capabilities adhere to the CLIA test reporting requirements and, therefore, propose that a Health IT Module presented for certification to this criterion must demonstrate that it can provide patient laboratory test reports that include the information for a test report specified in 42 CFR 493.1291(c)(1) through (7); the information related to reference intervals or normal values as specified in 42 CFR 493.1291(d); and the information for corrected reports as specified in 42 CFR 493.1291(k)(2).

Web Content Accessibility Guidelines (WCAG)

We reaffirm for stakeholders that the proposed 2015 Edition VDT criterion includes the WCAG 2.0 Level A (Level A) conformance requirements for the ''view'' capability. This is the same requirement we include in the 2014 Edition VDT criterion. We do, however, propose to modify the regulatory text hierarchy at § 170.204(a) to designate this standard at § 170.204(a)(1) instead of § 170.204(a). This would also require the 2014 Edition VDT certification criterion to be revised to correctly reference § 170.204(a)(1). We also seek comment on whether we should adopt WCAG 2.0 Level AA (Level AA) conformance requirements for the ''view'' capability included in the 2015 Edition VDT criterion (instead of Level A).

The most recent set of guidelines (WCAG 2.0) were published in 2008[147] and are organized under 4 central principles with testable success criteria: Perceivable, Operable, Understandable, and Robust. Each guideline offers 3 levels of conformance: A, AA, and AAA. Level A conformance corresponds to the most basic requirements for displaying Web content. Level AA conformance provides for a stronger level of accessibility by requiring conformance with Level A success criteria as well as Level AA specific success criteria. WCAG 2.0 Level AAA (Level AAA) conformance comprises the highest level of accessibility within the WCAG guidelines and includes all Level A and Level AA success criteria as well as success criteria unique to Level AAA.

In the 2014 Edition final rule (77 FR 54179) we considered public comment and ultimately adopted Level A for accessibility, but indicated our interest in raising this bar over time. As part of the Voluntary Edition proposed rule, we again proposed that health IT be compliant with Level AA for the

[145] CMS is generally responsible for regulatory laboratory oversight under CLIA, while CDC provides scientific and technical advice to CMS related to CLIA and OCR administers the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule.

[146] *https://www.federalregister.gov/articles/2014/02/06/2014-02280/clia-program-and-hipaa-privacy-rule-patients-access-to-test-reports.*

[147] *http://www.w3.org/TR/WCAG20/.*

proposed VDT certification criterion. We received a limited and mixed response to this proposal (79 FR 54465). In particular, some health IT developers opposed the increased level citing the cost and burden to reach Level AA, while others supported the move and offered no concerns. In both cases, health IT developers noted that WCAG conformance tools are somewhat sparse and that they have had difficulty finding viable tools.

Level AA provides a stronger level of accessibility and addresses areas of importance to the disabled community that are not included in Level A. For example, success criteria unique to Level AA include specifications of minimum contrast ratios for text and images of text, and a requirement that text can be resized without assistive technology up to 200 percent without loss of content or functionality. We recognize that Level AA is a step up from Level A, but also note that is has been nearly 3 years since we adopted Level A for the purposes of certification to the ''view'' capability. Accordingly, we once again request comment on the appropriateness of moving to Level AA for certification of the ''view'' capability included in the 2015 Edition VDT certification criterion.

We understand that there are not separate guidelines for ''mobile accessibility'' and that mobile is considered by the W3C Web Accessibility Initiative to be covered by the WCAG 2.0 guidelines.[148] Further, we would note that in September 2013, the W3C published a working group note consisting of ''Guidance on Applying WCAG 2.0 to Non-Web Information and Communications Technologies (WCAG2ICT).'' [149] We again request public comment (especially from health IT developers that have sought or considered certification to the 2014 Edition VDT certification criterion with a ''non-web'' application) on what, if any, challenges exist or have been encountered when applying the WCAG 2.0 standards.

''Transmit'' Request for Comment

In the 2014 Edition Release 2 final rule, we modified the ''transmit'' portion of the 2014 Edition VDT certification criterion to consistently allow for C–CDA ''content'' capabilities to be separately certified from ''transport'' capabilities using Direct. In so doing, we modified the transmit portion of the certification criterion to allow it to be met in one of two ways: (1) Following the Direct Project specification (for HISPs); or (2) following the Edge Protocol IG. Given this change to ''transmit'' that we have duplicated in the proposed 2015 Edition VDT certification criterion and our proposal to include an API capability as part of the proposed 2015 Edition VDT certification criterion, we request comment on whether stakeholders believe that it would be beneficial to include the Direct Project's Implementation Guide for Direct Project Trust Bundle Distribution specification [150] as part of certification to the first way described above (following the Direct Project specification (for HISPs)) for the 2015 Edition VDT certification criterion. This trust bundle specification's focuses on ''guidance on the packaging and distribution of Trust Bundles to facilitate scalable trust between Security/Trust Agents (STAs).'' As we understand, including this specification as part of certification could enable patient-facing technology to be configured to trust externally hosted bundles of S/MIME certificates. In addition, we have continued to hear concerns regarding the difficulties related to exchanging Direct messages across platforms and ''trust communities'' in the context of patient-directed transmissions. Therefore, we also request comments on whether any additional requirements are needed to support scalable trust between STAs as well as ways in which ONC, in collaboration with other industry stakeholders, could support or help coordinate a way to bridge any gaps.

C–CDA Creation Capability Request for Comment

We request public comment on a potential means to provide explicit implementation clarity and consistency as well as to further limit potential burdens on health IT developers. Specifically, should we limit the scope of C–CDA creation capability within this certification criterion to focus solely on the creation of a CCD document template based on the C–CDA Release 2.0? This approach could also have the benefit of creating clear expectations and predictability for other health IT developers who would then know the specific document template implemented for compliance with this criterion.

C–CDA Data Provenance Request for Comment

We refer readers to the request for comment under the same heading (''C–CDA Data Provenance Request for Comment'') in the ToC certification criterion earlier in this section of the preamble (section III). The request for comment focuses on the maturity of the HL7 IG for CDA Release 2: Data Provenance, Release 1 (US Realm) (DSTU) [151] and its potential use in connection with the C–CDA.

- *Clinical Summary*

We note that we are not proposing a 2015 Edition ''clinical summary'' certification criterion because past versions of this certification criterion were adopted in direct support of the EHR Incentive Programs. The proposals found in the EHR Incentive Programs Stage 3 proposed rule published elsewhere in this issue of the **Federal Register** rely on patients being provided with the ability to view, download, and transmit their health information via online access. Therefore, we believe the capabilities included in the 2015 Edition ''view, download, and transmit to 3rd party'' certification criterion appropriately and sufficiently support the proposals of the EHR Incentive Programs.

- *Secure Messaging*

2015 Edition Health IT Certification Criterion
§ 170.315(e)(2) (Secure messaging)

We propose to adopt a 2015 Edition ''secure messaging'' certification criterion that is unchanged in comparison to the 2014 Edition ''secure messaging'' criterion (§ 170.314(e)(3)).

- *Transmission to Immunization Registries*

2015 Edition Health IT Certification Criterion
§ 170.315(f)(1) (Transmission to immunization registries)

We propose to adopt a 2015 Edition ''transmission to immunization registries'' certification criterion that is revised in comparison to the 2014 Edition ''transmission to immunization registries'' criterion (§ 170.314(f)(2)). We propose to adopt an updated IG, require National Drug Codes (NDC) for recording administered vaccines, require CVX codes for historical vaccines, and require a Health IT Module presented for certification to

[148] *http://www.w3.org/WAI/mobile/.*

[149] *http://www.w3.org/TR/wcag2ict/.*

[150] *http://wiki.directproject.org/file/view/Implementation+Guide+for+Direct+Project+Trust+Bundle+Distribution+v1.0.pdf.*

[151] *http://wiki.hl7.org/index.php?title=HL7_Data_Provenance_Project_Space* and *http://gforge.hl7.org/gf/project/cbcc/frs/?action=FrsReleaseBrowse&frs_package_id=240.*

this criterion to be able to display an immunization history and forecast from an immunization registry. These proposals are described in more detail below.

Implementation Guide for Transmission to Immunization Registries

The 2014 Edition certification criterion for transmission to immunization registries at § 170.314(f)(2) references the following IG for immunization messaging: HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.4. Since the publication of the 2014 Edition final rule, the CDC has issued an updated IG (HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5) (October 2014) that promotes greater interoperability between immunization registries and health IT. Release 1.5 focuses on known issues from the previous release and revises certain HL7 message elements to reduce differences between states and jurisdictions for recording specific data elements. Specifically, Release 1.5: [152]

- Is organized into profiles, including separate profiles for VXU and ACK (acknowledgement) messages;
- Clarifies and tightens conformance statements;
- Corrects ACK (acknowledgment) messages to support improved messaging back to the EHR about the success/failure of a message; and
- Includes query and response changes such as V2.7.1 MSH user constraints, minimum requirements for a response message, and corrected profiles for response to errors and no match situations.

We believe these improvements are important to the IG and will continue to support our ultimate goal for this certification criterion—bidirectional immunization data exchange. Given the improvements included in the updated IG, we propose to adopt it at § 170.205(e)(4) and include it in the 2015 Edition ''transmission to immunization registries'' certification criterion.

National Drug Codes for Administered Vaccinations

In the Voluntary Edition proposed rule, we solicited comment for future editions on whether we should replace CVX codes for representing vaccines with NDC codes,[153] and on options for recording historical immunizations (79 FR 10908–9). NDC codes offer a number of benefits compared to CVX codes because:

- They can support pharmaceutical inventory management within immunization registries and are built into the provider's workflow;
- Are built into 2D barcodes, which have been successfully piloted for vaccines, and can improve quality and efficiency of data entry of information such as vaccine lot and expiration date; and
- Can improve patient safety with better specificity of vaccine formulation.

NDC codes also include packaging information as well as support linking to the unit of use and sale, whereas CVX codes do not provide this information as efficiently. These data elements are important for supporting vaccine inventory management.

Immunization registries are tightly linked to inventory management functions. This is largely due to the administration of the Vaccines for Children (VFC) program, a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay. CDC purchases vaccines at a discount and distributes them to grantees, which are state health departments and local and territorial public health agencies. The grantees distribute the VFC vaccines at no charge to private providers' offices and public health clinics registered as VFC providers. Because of the way this program is administered, immunization registries, which are maintained by public health agencies, have been developed to include vaccine inventory functions that help the grantees and providers manage their VFC vaccine stock. Due to the coupling of inventory functions within registries, many systems that can transmit immunization information to registries are also able to support these inventory management functions. NDC codes are used by many immunization registries to order vaccines and for inventory purposes.

We believe NDC codes for vaccines may be best suited to support immunization inventory management, as well as for providing the benefits stated above for 2D barcoding and patient safety. Both the HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5 and the C–CDA Release 2.0 IG support coding of immunizations using both CVX and NDC codes. CDC also provides a publicly available mapping of NDC codes for vaccines to CVX codes.[154]

NDC codes for vaccines include a portion that identifies the product, and thus cannot be used to code historical vaccinations of unknown formulation. Historical vaccinations are self-reported vaccinations given prior to the office visit. Patients can report historical vaccinations to providers without supporting documentation, such as a written or electronic vaccination history, and therefore the provider does not know the manufacturer and/or formulation of the product. In terms of options for recording historical vaccinations of unspecified/unknown formulation, we solicited comments on two options in the Voluntary Edition proposed rule:

- Option 1: Continue to use CVX codes for historical vaccinations only;
- Option 2: Use the NDC syntax and create a new value set for the product portion of the code for vaccines of unspecified formula (*e.g.,* influenza vaccine of unspecified formula) for historical vaccinations (resulting in an ''NDC-like'' code).

The majority of commenters were opposed to Option 2 for creating an ''NDC-like'' code. Commenters believed it would add complexity to coding NDC codes and be burdensome to maintain in the long-term. We agree with commenters and therefore believe Option 1 is a more viable solution for recording historical vaccinations. We believe health IT should be able to record historical vaccinations to provide the most complete record possible for a provider to use in determining which vaccines a patient may need.

We received comments that recommended we consider moving to RxNorm® codes for immunizations. However, RxNorm® does not support inventory management nor does it support recording historical vaccinations. Therefore, we do not believe RxNorm® is the best available option for coding vaccinations at this time.

We also received public comment that, in certain circumstances, NDC codes can be reused. Commenters expressed concerned about potential confusion for vaccine products when NDC codes are reused. In consultation with FDA, we understand that FDA does not intend to allow reuse of NDC codes for vaccine products going forward. Thus, we do not believe that reuse of NDC codes will be an issue for vaccine coding.

Given the discussion above on the benefits of NDC codes for coding vaccinations and in consideration of public comment, we propose to require for certification that a Health IT Module be able to electronically create

[152] *http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf.*

[153] *http://www.fda.gov/drugs/informationondrugs/ucm142438.htm.*

[154] *http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=ndc.* See also: *http://www2a.cdc.gov/vaccines/iis/iisstandards/ndc_tableaccess.asp.*

immunization information for electronic transmission to immunization registries using NDC codes for vaccines administered (*i.e.,* the National Drug Code Directory—Vaccine Codes, updates through January 15, 2015 [155]). For historical vaccines, we propose to continue the use of CVX codes and propose to adopt the HL7 Standard Code Set CVX—Vaccines Administered, updates through February 2, 2015,[156] as the baseline version for certification to the 2015 Edition. We refer readers to section III.A.2.d (''Minimum Standards'' Code Sets) for further discussion of our proposal to adopt the National Drug Code Directory—Vaccine Codes as a minimum standards code set and the ''January 15, 2015 version,'' or potentially a newer version if released before a subsequent final rule, as the baseline for certification to the 2015 Edition. We also refer readers to section III.A.2.d (''Minimum Standards'' Code Sets) for further discussion of our adoption of CVX codes as a minimum standards code set and our proposal to adopt the ''February 2, 2015 version,'' or potentially a newer version if released before a subsequent final rule, as the baseline for certification to the 2015 Edition.

In addition to soliciting comments on this proposal, we solicit comment on whether we should allow use of NDC codes for administered vaccines as an option for certification, but continue to require CVX codes for administered vaccines for the 2015 Edition. Allowing for optional use of NDC codes for administered vaccines could provide health IT developers and health care providers an implementation period before we would consider requiring NDC codes for administered vaccines. We also solicit comment on whether we should require CVX plus the HL7 Standard Code Set MVX—Manufacturers of Vaccines Code Set (October 30, 2014 version) [157] as an alternative to NDC codes for administered vaccines. MVX codes identify the manufacturer of a vaccine and support recording the vaccine at the trade name level when paired with the CVX code. MVX codes do not, however, independently include the trade name, package, or unit of use/unit of sale. CVX codes plus MVX codes could provide more information than CVX codes alone, but not as much information as NDC codes. As part of this comment solicitation, we also invite comments on the implementation burden for health IT developers and health care providers of requiring CVX plus MVX codes versus NDC codes for administered vaccines.

Immunization History and Forecast

In the Voluntary Edition proposed rule, we solicited comment on the maturity of bidirectional immunization data exchange activities and whether we should propose to include bidirectional immunization exchange in our certification rules. Commenters supported inclusion of bidirectional immunization data exchange. We understand that the HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5 we are proposing to adopt for this criterion provides improvements that support bidirectional exchange between health IT and immunization registries, including segments for querying a registry, receiving information, and sending a response to the registry. Additionally, we received comments specifically recommending that immunization forecast information and CDS guidance provide results in accordance with the Advisory Committee on Immunization Practice's (ACIP) [158] recommendations.

We believe that bidirectional exchange between health IT and immunization registries is important for patient safety and improved care. Immunization registries can provide information on a patient's immunization history to complement the data in the EHR. Immunization registries also provide immunization forecasting recommendations according to the ACIP's recommendations. This information allows for the provider to access the most complete and up-to-date information on a patient's immunization history to inform discussions about what vaccines a patient may need based on nationally recommended immunization recommendations.

Provided the discussion above, we propose that, for certification to this criterion, a Health IT Module would need to enable a user to request, access, and display a patient's immunization history and forecast from an immunization registry in accordance with the HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5. We welcome comment on this proposal. We also welcome comments on whether we should include an immunization history information reconciliation capability in this criterion and the factors we should consider regarding the reconciliation of immunization history information.

Exchange of the Common Clinical Data Set—NDC and CVX Codes

For transmission of immunization information across settings using the C–CDA standard, NDC codes carry more information than CVX codes, specifically for inventory management and safety functions (*e.g.,* trade name, package, and unit of use/unit of sale). For quality reporting of immunization coverage data using the QRDA Category I standard, inventory management data may not be needed, and therefore a CVX code is sufficient for submission of quality reporting data. However, ONC is supportive of moving towards collection of vaccine administration data within the EHR with the patient's clinical data regardless of the requirements in the QRDA Category I standard. We believe it is appropriate to use mapping from NDC codes to CVX codes and a mapping table is available.[159] We understand that the C–CDA Release 2.0 can support NDC codes as a translational data element, but the CVX code is required to accompany it. The additional information NDC codes contain could assist with vaccine tracking for clinical trials and adverse events. Therefore, we propose in a later section of this rule to include the representation of immunizations in both CVX codes and NDC codes as part of the ''Common Clinical Data Set'' definition for certification to the 2015 Edition. Please see section III.B.3 ''Common Clinical Data Set'' of this preamble for further discussion of this associated proposal. We note that this means that a Health IT Module certified to certification criteria that include the Common Clinical Data Set (*e.g.,* the ToC criterion) must demonstrate the capability to represent immunizations in CVX codes and NDC codes. This approach ensures that health IT would be able to support a provider's attempt to send immunization information that includes NDC information.

Immunization Information Certification Criterion

In response to the Voluntary Edition proposed rule, we received comments recommending we discontinue the ''immunization information'' certification criterion for future editions because the necessary data elements are enumerated in the IG for reporting to immunization registries required for the

[155] *http://www2a.cdc.gov/vaccines/iis/iisstandards/ndc_tableaccess.asp.*

[156] *http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx.*

[157] *http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=mvx.*

[158] *http://www.cdc.gov/vaccines/acip/.*

[159] *http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=ndc.* See also: *http://www2a.cdc.gov/vaccines/iis/iisstandards/ndc_tableaccess.asp.*

''transmission to immunization registries'' criterion. These commenters did not see any additional value in having a standalone certification criterion for ''immunization information'' as the value lies in being able to transmit the immunization message. We agree with these comments. Therefore, we are not proposing an ''immunization information'' criterion as part of the 2015 Edition. We welcome comments on this approach.

• *Transmission to Public Health Agencies—Syndromic Surveillance*

2015 Edition EHR Certification Criterion
§ 170.315(f)(2) (Transmission to public health agencies—syndromic surveillance)

We propose to adopt a 2015 Edition certification criterion for transmission of syndromic surveillance to public health agencies that is revised in comparison to the 2014 Edition version (§ 170.314(f)(3)) for the inpatient setting. We note, however, that this proposed certification criterion is unchanged (for the purposes of gap certification) for the ambulatory setting. As discussed in the 2014 Edition Release 2 final rule, we understand that ambulatory providers may be using different methods for sending syndromic surveillance information to public health agencies, including HL7 2.5.1 and query-based messages (79 FR 54439–54441). It is our understanding that these methods are still being implemented and refined within the industry and the public health community. Therefore, given the varied adoption of methods for transmitting syndromic surveillance information to public health agencies from ambulatory settings, we propose to continue to distinguish between ambulatory and emergency department, urgent care, and inpatient settings.

Emergency Department, Urgent Care, and Inpatient Settings

We propose to adopt the PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent, Ambulatory Care, and Inpatient Settings, Release 2.0, September 2014 (''Release 2.0'').[160] Release 2.0 provides improvements over previous versions by:

• Re-purposing of the HL7 2.5.1 messaging structure for all type of messages/trigger events, and combining all specifications in one profile;

• Re-structuring chapters, making them more concise and placing supporting information into Appendixes;

• Adding more implementation comments and better field name descriptions within segment profile attributes;

• Making examples better aligned to the business process;

• Adding new conformance statements that simplify testing of messages;

• Making more user-friendly navigation through the document (adding a more detailed Table of Contents, updating a format of implementation comments, etc.);

• Simplifying collection and management of data by addressing requests for only using a text format for the ''Chief Complaint/Reason for Visit'' Data Element; and

• Correcting errors that were discovered in Version 1.9.

We believe these improvements are important to the IG and will continue to support interoperability and data exchange of syndromic surveillance information. As we adopted Release 1.8 of the IG in 2012 for the 2014 Edition, we believe the industry has had sufficient time to implement Release 1.8 and could benefit from the updates in Release 2.0. Release 2.0 also updates errors and known issues from Release 1.9 that commenters noted in response to the Voluntary Edition proposed rule as discussed in the Voluntary Edition final rule (79 FR 54440). Given the improvements included in Release 2.0 of the IG, we propose to adopt it at § 170.205(d)(4) and include it in the 2015 Edition ''transmission to public health agencies—syndromic surveillance'' certification criterion for emergency department, urgent care, and inpatient settings.

Ambulatory Syndromic Surveillance

We propose to permit, for ambulatory setting certification, the use of any electronic means for sending syndromic surveillance data to public health agencies as well as optional certification to certain syndromic surveillance data elements. In the 2014 Edition Release 2 final rule, we adopted a certification criterion for ambulatory syndromic surveillance at § 170.314(f)(7) that permits use of any electronic means of sending syndromic surveillance data to public health agencies for ambulatory settings (79 FR 54440–01). We adopted this criterion to provide EPs under the EHR Incentive Programs to meet the Stage 2 syndromic surveillance objective with the use of CEHRT. Because there were no IGs to support HL7 2.5.1 messaging or query-based syndromic surveillance for ambulatory settings, we expanded our policy to provide more flexibility to EPs to meet the syndromic surveillance objective.

As part of the 2014 Edition criterion, we also provide the option for technology presented for certification to demonstrate that it can electronically produce syndromic surveillance information that contains patient demographics, provider specialty, provider address, problem list, vital signs, laboratory results, procedures, medications, and insurance. Public health agencies and stakeholders that piloted query-based models for transmitting ambulatory syndromic surveillance data send all of these data elements. We offered this optional list of data elements for certification to provide clarity and a path forward to health IT developers on the data elements they should focus on for creating syndrome-based public health transmissions in support of query-based models, including any potential certification requirements introduced through future rulemaking. Due to the continued lack of mature IGs at this time, we propose to take the same approach for 2015 Edition syndromic surveillance certification for the ambulatory setting.

• *Transmission to Public Health Agencies—Reportable Laboratory Tests and Values/Results*

2015 Edition Health IT Certification Criterion
§ 170.315(f)(3) (Transmission to public health agencies—reportable laboratory tests and values/results)

We propose to adopt a 2015 Edition certification criterion that is revised in comparison to the 2014 Edition ''transmission of reportable laboratory tests and values/results'' criterion (§ 170.314(f)(4)). We have named this criterion ''transmission to public health agencies—reportable laboratory tests and values/results'' to clearly convey the capabilities included in this criterion as they relate to the intended recipient of the data. We propose to include and adopt an updated IG for laboratory reporting to public health, an updated version of SNOMED CT®, and an updated version of LOINC®. We also propose to make a technical amendment to the regulation text for the 2014 Edition criterion in order to have it continue to reference the appropriate standard and implementation specifications[161] after we restructure

[160] *http://www.cdc.gov/phin/library/guides/SyndrSurvMessagGuide2_MessagingGuide_PHN.pdf*

[161] HL7 2.5.1 and HL7 Version 2.5.1: Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 with Errata

Continued

the regulatory text hierarchy at § 170.205(g) to accommodate our 2015 Edition proposal.

CDC worked in conjunction with the HL7 Public Health Emergency Response Workgroup to develop an updated IG (HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm), DSTU R1.1, 2014 or ''Release 2, DSTU R1.1'') that address technical corrections and clarifications for interoperability with laboratory orders and other laboratory domain implementation guides. Specifically, ''Release 2, DSTU R1.1'': [162]

- Corrects errata;
- Updates Objective Identifiers;
- Applies conformance statements from the LRI DSTU;
- Provides technical corrections; and
- Updates usage for consistent treatment of modifier fields.

As we adopted Release 1 of the IG in 2012 for the 2014 Edition, we believe the industry has had sufficient time to implement Release 1 and could benefit from the updates in ''Release 2, DSTU R1.1.'' Given the improvements included in the updated IG (Release 2, DSTU R1.1), we propose to adopt it at § 170.205(g)(2) and include it in the 2015 Edition ''transmission of reportable laboratory tests and values/results'' certification criterion at § 170.315(f)(3). As noted above, to properly codify this proposal in regulation, we would have to modify the regulatory text hierarchy in § 170.205(g) to designate the standard and implementation specifications referenced by the 2014 Edition ''transmission of reportable laboratory tests and values/results'' certification criterion at § 170.205(g)(1) instead of its current designation at § 170.205(g).

We propose to include the September 2014 Release of the U.S. Edition of SNOMED CT® and LOINC® version 2.50 in this criterion. We refer readers to section III.A.2.d (''Minimum Standards'' Code Sets) for further discussion of our adoption of SNOMED CT® and LOINC® as minimum standards code sets and our proposals to adopt the versions cited above, or potentially newer versions if released before a subsequent final rule, as the baselines for certification to the 2015 Edition.

- Transmission to Cancer Registries

2015 Edition Health IT Certification Criterion

§ 170.315(f)(4) (Transmission to cancer registries)

We propose to adopt a 2015 Edition ''transmission to cancer registries'' certification criterion that is revised in comparison to the 2014 Edition ''transmission to cancer registries'' certification criterion (§ 170.314(f)(6)). We propose to adopt an HL7 version cancer reporting IG, adopt an updated version of SNOMED CT®, and adopt an updated version of LOINC®. We also propose to make a technical amendment to the regulation text for the 2014 Edition certification criterion so that it continues to reference the appropriate standard [163] in the regulatory text hierarchy at § 170.205(i), while accommodating our 2015 Edition proposal. Specifically, we propose to modify the 2014 Edition certification criterion to reference § 170.205(i)(1) to establish the regulatory text hierarchy necessary to accommodate the standard and IG referenced by the proposed 2015 Edition certification criterion.

The 2014 Edition ''transmission to cancer registries'' criterion at § 170.314(f)(6) references the following IG for cancer reporting: Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA), Release 1.0. Since the publication of the 2014 Edition Final Rule, CDC worked with HL7 to introduce the IG to the standards developing organization processes. In doing so, an updated IG has been developed to address technical corrections and clarifications for interoperability with EHRs and cancer registries (HL7 Implementation Guide for CDA© Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers Release 1 or ''HL7 IG Release 1''). Specifically, HL7 IG Release 1: [164]

- Aligns with C–CDA Release 2.0 templates, where possible;
- Adds new data elements, including grade, pathologic TNM stage,[165] family history of illness, height and weight, discrete radiation oncology items, planned medications, and planned procedures;
- Changes optionality for some data elements in response to cancer community input and to align with C–CDA Release 2.0 templates;
- Improves documentation and aligns conformance statements with table constraints;
- Adds some new vocabulary links and a new reportability list for ICD–10–CM;
- Fixes some within-document references;
- Fixes some LOINC® codes;
- Fixes some Code System and Value Set Object Identifiers;
- Fixes some conformance verbs;
- Improves sample XML snippets;
- Fixes some conformance verbs and data element names in Appendix B ''Ambulatory Healthcare Provider Cancer Event Report—Data Elements''; and
- Fixes a value in the value set.

These improvements will continue to promote interoperability between health IT and cancer registries for improved cancer case reporting to public health agencies. As we adopted the non-HL7 Release 1 of the IG in 2012 for the 2014 Edition, we believe the industry has had sufficient time to implement that IG and could benefit from the updates in HL7 IG Release 1. Therefore, given the improvements that will be included in HL7 IG Release 1 as described above, we propose to adopt it at § 170.205(i)(2) and include it in the proposed 2015 Edition ''transmission to cancer registries'' certification criterion.

We propose to include the September 2014 Release of the U.S. Edition of SNOMED CT® and LOINC® version 2.50 in this criterion. We refer readers to section III.A.2.d (''Minimum Standards'' Code Sets) for further discussion of our adoption of SNOMED CT® and LOINC® as minimum standards code sets and our proposals to adopt the versions cited above, or potentially newer versions if released before a subsequent final rule, as the baselines for certification to the 2015 Edition.

Cancer Case Information

In response to the Voluntary Edition proposed rule, we received comments recommending we discontinue proposing and adopting a ''cancer case information'' certification criterion for future editions because the necessary data elements are enumerated in the IG for reporting to cancer registries that we include in editions of ''transmission to cancer registries'' criteria. We agree with this assessment. Therefore, we are not proposing a 2015 Edition ''cancer case information'' certification criterion

and Clarifications and ELR 2.5.1 Clarification Document for EHR Technology Certification.

[162] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=329.*

[163] *Standard.* HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition (incorporated by reference in § 170.299). *Implementation specifications.* Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA), Release 1.0 (incorporated by reference in § 170.299).

[164] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=383.*

[165] The TNM Classification of Malignant Tumours (TNM) is a cancer staging system that describes the extent of a person's cancer.

similar to the one we adopted for the 2014 Edition. We welcome comments on this approach.

• *Transmission to Public Health Agencies—Case Reporting*

2015 Edition Health IT Certification Criterion

§ 170.315(f)(5) (Transmission to public health agencies—case reporting)

We propose to adopt a new certification criterion in the 2015 Edition for electronic transmission of case reporting information to public health agencies.

Health IT standards continue to evolve to address new and emerging use cases for health care. The utility of health IT for supplemental purposes has been limited due to a lack of uniformity in the terminology and definitions of data elements across health IT systems. This limitation is compounded by the fact that provider workflow often records patient information in unstructured free-text well after episodes of care. Linking data in EHR systems with other data in a uniform and structured way could accelerate quality and safety improvement, population health, and research.

Toward this end, the S&I Structured Data Capture [166] (SDC) initiative is a multi-stakeholder group working on standards-based architecture so that a set of structured data can be accessed from health IT and stored for merger with comparable data for other relevant purposes. The SDC initiative is developing a set of standards that will enable health IT to capture and store structured data. These standards will build upon and incorporate existing standards, including the IHE Retrieve Form for Data Capture (RFD) profile. As part of this work, the SDC initiative has developed a surveillance case report form for public health reporting of notifiable diseases as part of the IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation (September 5, 2014) standard.[167] The case report form can be further specified and used to electronically report vital statistics, vaccine adverse event reporting, school/camp/daycare physical, early hearing detection and intervention/newborn hearing screening, and cancer registry reporting, among other public health reporting data.

We believe that case reporting from health care providers to public health agencies could be more real-time, structured, and efficient through the use of the standard case report form that the SDC initiative has developed. Therefore, we propose to adopt a certification criterion for electronic transmission of case reporting information to public health that would require a Health IT Module to be able to electronically create case reporting information for electronic transmission in accordance with the IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation (September 5, 2014) standard, which we propose to adopt at § 170.205(q)(1). As mentioned above, this standard and our proposal include compliance with other existing standards. One such standard is the CDA Release 2.0, which is a foundational standard for use in sending and receiving case reporting information.

To note, for testing to this criterion, a Health IT Module would need to demonstrate that it can create and send a constrained transition of care document to a public health agency, accept a URL in return, be able to direct end users to the URL, and adhere to the security requirements for the transmission of this information.

We recognize that the Fast Health Interoperability Resource (FHIR®) REST API and FHIR-based standard specifications will likely play a role in an interoperable health IT architecture. FHIR resources that implement SDC concepts and support the use of case reporting to public health would likely play a role in that scenario. The current HL7 FHIR Implementation Guide: Structure Data Capture (SDC), Release 1 [168] is a ''draft for comment'' with a DSTU ballot planned for mid-2015. Given this trajectory, we solicit comment on whether we should consider adopting the HL7 FHIR Implementation Guide: SDC DSTU that will be balloted in mid-2015 in place of, or together with, the IHE Quality, Research, and Public Health Technical Framework Supplement. We are aware of a proposed HL7 working group known as the Healthcare Standards Integration Workgroup that will collaborate on FHIR resources considered co-owned with the IHE–HL7 Joint Workgroup [169] within IHE. The implementation guides created from the S&I SDC Initiative is part of this joint workgroup's area of responsibility. Therefore, we intend to work with these coordinated efforts to ensure a complementary and coordinated approach for case reporting using SDC.

• *Transmission to Public Health Agencies—Antimicrobial Use and Resistance Reporting*

2015 Edition Health IT Certification Criterion

§ 170.315(f)(6) (Transmission to public health agencies—antimicrobial use and resistance reporting)

We propose to adopt a new 2015 Edition certification criterion for transmission of antimicrobial use and resistance data to public health agencies that would require a Health IT Module to be able to electronically create antimicrobial use and resistance reporting information for electronic transmission in accordance with specific sections of the HL7 Implementation Guide for CDA ® Release 2—Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm (August 2013).

Collection and analysis of data on antimicrobial use and antimicrobial resistance are important components of antimicrobial stewardship programs throughout the nation and efforts by health care organizations and public health agencies aimed at detecting, preventing, and responding to resistant pathogens. Surveillance provides vital data for use by health care facilities, local, state, and federal agencies, research and development teams, policymakers, and the public. Electronic submission of antimicrobial use and antimicrobial resistance data to a public health registry can promote timely, accurate, and complete reporting, particularly if data is extracted from health IT systems and delivered using well established data exchange standards to a public health registry. The HL7 Implementation Guide for CDA ® Release 2—Level 3: Healthcare Associated Infection Reports, Release 1—US Realm—August 2013 [170] (''HAI IG'') is an ANSI-approved standard for electronic reporting of antimicrobial use and antimicrobial resistance data to the CDC's National Healthcare Safety Network (NHSN), the largest health care-associated infection (HAI) reporting system in the United States with over 9,000 health care facilities participating. The HAI IG provides details for reporting from EPs, eligible hospitals, and CAHs.

We propose to test and certify a Health IT Module for conformance with the following sections of the IG:

[166] *http://wiki.siframework.org/Structured+Data+Capture+Initiative.*

[167] *http://www.ihe.net/uploadedFiles/Documents/QRPH/IHE_QRPH_Suppl_SDC.pdf.*

[168] *http://hl7.org/implement/standards/FHIR-Develop/sdc.html.*

[169] *http://wiki.ihe.net/index.php?title=IHE-HL7_Joint_Workgroup.*

[170] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=20.*

• HAI Antimicrobial Use and Resistance (AUR) Antimicrobial Resistance Option (ARO) Report (Numerator) specific document template in Section 2.1.2.1 (pages 69–72);

• Antimicrobial Resistance Option (ARO) Summary Report (Denominator) specific document template in Section 2.1.1.1 (pages 54–56); and

• Antimicrobial Use (AUP) Summary Report (Numerator and Denominator) specific document template in Section 2.1.1.2 (pages 56–58).

We propose to adopt these specific sections of the IG in § 170.205(r)(1). Note that the specific document templates referenced above include conformance to named constraints in other parts of the IG, and we would expect a Health IT Module presented for certification to this criterion to conform to all named constraints within the specified document template.

• *Transmission to Public Health Agencies—Health Care Surveys*

2015 Edition Health IT Certification Criterion
§ 170.315(f)(7) (Transmission to public health agencies—health care surveys)

We propose to adopt a new 2015 Edition certification criterion for transmission of health care surveys to public health agencies. We propose to adopt a certification criterion for transmission of health care survey information to public health agencies that would require a Health IT Module to be able to create health care survey information for electronic transmission in accordance with the HL7 Implementation Guide for CDA ® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, Draft Standard for Trial Use (December 2014),[171] which we propose to adopt at § 170.205(s)(1).

The National Ambulatory Medical Care Survey (NAMCS) is a national survey designed to meet the need for objective, reliable information about the provision and use of ambulatory medical care services in the U.S. Findings are based on a sample of visits to non-federal employed office-based physicians who are primarily engaged in direct patient care.

The National Hospital Ambulatory Medical Care Survey (NHAMCS) is designed to collect data on the utilization and provision of ambulatory care services in hospital emergency and outpatient departments. Findings are based on a national sample of visits to the emergency departments and outpatient departments of general and short-stay hospitals.

The kinds of data contained in this survey are:

• Patient demographics such as date of birth, sex, race and ethnicity;

• Vital signs such as height, weight and blood pressure;

• Reason for visit or chief complaint;

• Diagnoses associated with the visit;

• Chronic conditions that the patient has at the time of the visit;

• Procedures provided or ordered;

• Diagnostic tests ordered or provided;

• New or continued medications at the time of the visit; and

• Other variables such as tobacco use, whether the provider is the patient's primary care provider, how many times has the patient been seen in the practice in the past 12 months, which type of providers were seen at the visit, amount of time spent with the provider, and visit disposition.

Automating the survey process using the CDA standard streamlines the collection of data and increases the sample pool by allowing all providers who want to participate in the surveys to do so. The HL7 Implementation Guide for CDA ® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, Draft Standard for Trial Use (December 2014) defines the electronic submission of the data to the CDC. We clarify that the IG is intended for the transmission of survey data for both the NAMCS (*e.g.,* for ambulatory medical care settings) and NHAMCS (*e.g.,* for hospital ambulatory settings including emergency departments and outpatient departments). Templates included in this IG align with the C–CDA standard. Additionally, the templates in this IG expand on the scope of the original NAMCS and NHAMCS survey data elements and do not constrain the data collected to the narrow lists on the survey instruments; rather they allow any service, procedure or diagnosis that has been recorded.

• *Automated Numerator Recording*

2015 Edition Health IT Certification Criterion
§ 170.315(g)(1) (Automated numerator recording)

We propose to adopt a 2015 Edition ''automated numerator recording'' certification criterion that is unchanged in comparison to the 2014 Edition ''automated numerator recording'' criterion. We note, however, that the test procedure for this criterion would be different from the 2014 Edition ''automated numerator recording'' certification criterion in order to remain consistent with the applicable objectives and measures required under the EHR Incentive Programs.

• *Automated Measure Calculation*

2015 Edition Health IT Certification Criterion
§ 170.315(g)(2) (Automated measure calculation)

We propose to adopt a 2015 Edition ''automated measure calculation'' certification criterion that is unchanged in comparison to the 2014 Edition ''automated measure calculation'' criterion. We propose to apply the guidance provided for the 2014 Edition ''automated measure calculation'' certification criterion in the 2014 Edition final rule in that a Health IT Module must be able to support all CMS-acceptable approaches for measuring a numerator and denominator in order for the Health IT Module to meet the proposed 2015 Edition ''automated measure calculation'' certification criterion.[172] We also propose that the interpretation of the 2014 Edition ''automated measure calculation'' certification criterion in FAQ 32 [173] would apply to the proposed 2015 Edition ''automated measure calculation'' certification criterion.

We note that the test procedure for this criterion would be different from the 2014 Edition ''automated measure calculation'' certification criterion in order to remain consistent with the applicable objectives and measures required under the EHR Incentive Programs.

• *Safety-Enhanced Design*

2015 Edition Health IT Certification Criterion
§ 170.315(g)(3) (Safety-enhanced design)

We propose to adopt a 2015 Edition ''safety-enhanced design'' (SED) certification criterion that is revised in comparison to the 2014 Edition ''safety-enhanced design'' criterion. We propose to add certification criteria to this criterion that we believe include capabilities that pose a risk for patient harm and, therefore, an opportunity for error prevention. We propose to provide further compliance clarity for the data elements described in NISTIR 7742 [174] that are required to be submitted as part of the summative usability test results and to specifically include these data

[171] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=385.*

[172] 77 FR 54244–54245.

[173] *http://www.healthit.gov/policy-researchers-implementers/32-question-11-12-032.*

[174] *http://www.nist.gov/manuscript-publication-search.cfm?pub_id=907312.* NISTIT 7742 is a valid and reliable publication for user-centered design processes.

elements as part of the certification criterion.

Certification Criteria Identified in the SED Criterion for UCD Processes

We propose to include seventeen (17) certification criteria (seven are new) in the 2015 Edition SED certification criterion, as listed below (emphasis added for new criteria). For each of the referenced certification criteria and their corresponding capabilities presented for certification, user-centered design (UCD) processes must have been applied in order satisfy this certification criterion.

- § 170.315(a)(1) Computerized provider order entry—medications
- § 170.315(a)(2) Computerized provider order entry—laboratory
- § 170.315(a)(3) Computerized provider order entry—diagnostic imaging
- § 170.315(a)(4) Drug-drug, drug-allergy interaction checks
- *§ 170.315(a)(5) Demographics*
- *§ 170.315(a)(6) Vital signs, BMI, and growth charts*
- *§ 170.315(a)(7) Problem list*
- § 170.315(a)(8) Medication list
- § 170.315(a)(9) Medication allergy list
- § 170.315(a)(10) Clinical decision support
- § 170.315(a)(18) Electronic medication administration record
- *§ 170.315(a)(20) Implantable device list*
- *§ 170.315(a)(22) Decision support—knowledge artifact*
- *§ 170.315(a)(23) Decision support—service*
- § 170.315(b)(2) Clinical information reconciliation and incorporation
- § 170.315(b)(3) Electronic prescribing
- *§ 170.315(b)(4) Incorporate laboratory tests/results*

The continued submission of summative usability test results promotes transparency and can foster health IT developer competition, spur innovation, and enhance patient safety. With this in mind, we also seek comment on whether there are other certification criteria that we omitted from this proposed SED criterion that commenters believe should be included.

NISTIR 7742 Submission Requirements

In the 2014 Edition final rule, we specified that the information listed below from the NISTIR 7742 ''Customized Common Industry Format Template for Electronic Health Record Usability Testing'' (NIST 7742) [175] was required to be submitted for each and every one of the criteria specified in the 2014 Edition SED criterion (77 FR 54188). For the 2015 Edition SED criterion, we propose to include the information below in the regulation text of the 2015 Edition SED criterion to provide more clarity and specificity for the information requested to be provided to demonstrate compliance with this certification criterion. The findings that would be required to be submitted for each and every one of the criteria specified in the 2015 Edition SED criterion (and become part of the test results publicly available on the Certified Health IT Product List (CHPL)) are:

- Name and version of the product
- Date and location of the test
- Test environment
- Description of the intended users
- Total number of participants
- Description of participants as follows:
  - Sex
  - Age
  - Education
  - Occupation/role
  - Professional experience
  - Computer experience
  - Product experience
- Description of the user tasks that were tested and association of each task to corresponding certification criteria
- List of the specific metrics captured during the testing
  - Task Success (%)
  - Task Failures (%)
  - Task Standard Deviations (%)
  - Task Performance Time
  - User Satisfaction Rating (Scale with 1 as very difficult and 5 as very easy)
- Test results for each task using metrics listed above
- Results and data analysis narrative:
  - Major test finding
  - Effectiveness
  - Efficiency
  - Satisfaction
  - Areas for improvement

There are illustrative tables on pages 11 and 20 in NISTIR 7742 that provide examples of the presentation of test participants and test results data. We specify that all of the data elements and sections specified above must be completed, including ''major findings'' and ''areas for improvement.'' Pages 18 and 19 of the NISTIR 7742 contain a table with suggested instructions for data scoring specifically noting that for task success, a task is counted as successful if the participant was able to achieve the correct outcome without assistance and within the time allotted on a per task basis. Likewise, for task satisfaction a 5 point Likert scale is recommended with scores ranging from ''1—very difficult'' to ''5—very easy.''

The NISTIR 7742 includes several sections: Executive Summary, Introduction, Method, and Results. In each of these sections, there are required data elements—and some of these elements call for the reporting of the number of study participants, their level of experience with EHR technology and other pertinent details.

We recommend following NISTIR 7804 [176] ''Technical Evaluation, Testing, and Validation of the Usability of Electronic Health Records'' for human factors validation testing of the final product to be certified. In accordance with this guidance, we recommend a minimum of 15 representative test participants for each category of anticipated clinical end users who conduct critical tasks where the user interface design could impact patient safety (*e.g.,* physicians, nurse practitioners, physician assistants, nurses, etc.). The cohort of users who are selected as participants will vary with the product and its intended users; however, the cohort should not include employees of the developer company. We specify the submission of demographic characteristics of the test participants comparable to the table on page 11 of NISTIR 7742 because it is important that the test participant characteristics reflect the audience of current and future users. In accordance with NISTIR 7804 (page 8), we recommend that the test scenarios be based upon an analysis of critical use risks for patient safety which can be mitigated or eliminated by improvements to the user interface design.

In lieu of simply providing guidance on the number of, and user cohort for, test participants, we request comment on whether we should establish a minimum number(s) and user cohort(s) for test participants for the purposes of testing and certification to the 2015 Edition under the ONC Health IT Certification Program.

New Requirements and Compliance Guidance

As we noted in the 2014 Edition final rule (77 FR 54188), examples of method(s) that could be employed for UCD include ISO 9241–11, ISO 13407, ISO 16982, ISO/IEC 62366, ISO 9241–210 and NISTIR 7741. The UCD process selected by a health IT developer need not be listed in the examples provided in order to be acceptable. We do, however, strongly advise health IT developers to select an industry standard process because compliance

[175] *http://www.nist.gov/manuscript-publication-search.cfm?pub_id=907312.*

[176] *http://www.nist.gov/customcf/get_pdf.cfm?pub_id=909701.*

with this certification criterion requires submission of the name, description, and citation (URL and/or publication citation) of the process that was selected. In the event that a health IT developer selects a UCD process that is not an industry standard (that is, not developed by a voluntary consensus standards organization), but is based on one or more industry standard processes, the developer may name the process(es) and provide an outline of the process in addition to a short description as well as an explanation of the reason(s) why use of any of the existing UCD standards was impractical.

Health IT developers can perform many iterations of the usability testing, but the submission that is ultimately provided for summative usability testing and certification must be an expression of a final iteration. In addition, we expect the test scenarios used to be submitted as part of the test results. Last, we note that we do not expect developers to include trade secrets or proprietary information in the test results.

Request for Comment on Summative Testing

We understand that some health IT developers are concerned that the summative testing report may not adequately reflect the design research that has been performed throughout a product's lifecycle. We request public comment regarding options that we might consider in addition to—or as alternatives to—summative testing. For example, if formative testing reflects a thorough process that has tested and improved the usability of a product, could a standardized report of the formative testing be submitted for one or more of the 17 certification criteria for which summative testing is now required? What would be the requirements for this formative testing report, and how would purchasers evaluate these reports?

Retesting and Certification

We believe that ONC–ACB determinations related to the ongoing applicability of the SED certification criterion to certified health IT for the purposes of inherited certified status (§ 170.550(h)), adaptations and other updates would be based on the extent of changes to user-interface aspects of one or more capabilities to which UCD had previously been applied. We believe that ONC–ACBs should be notified when applicable changes to user-interface aspects occur. Therefore, we include these types of changes in our proposal to address adaptations and updates under the ONC–ACB Principles of Proper Conduct (§ 170.523). Please see section IV.D.6 of this preamble for further discussion of this proposal.

• *Quality Management System*

2015 Edition Health IT Certification Criterion
§ 170.315(g)(4) (Quality management system)

We propose to adopt a 2015 Edition ''quality management system'' certification criterion that is revised in comparison to the 2014 Edition ''quality management system'' criterion. We propose to require, for a Health IT Module presented for certification, the identification of the Quality Management System (QMS) used in the development, testing, implementation, and maintenance of capabilities certified under the ONC Health IT Certification Program. The identified QMS must be:

• Compliant with a quality management system established by the federal government or a standards developing organization; or

• mapped to one or more quality management systems established by the federal government or standards developing organization(s).

In the 2014 Edition final rule, we stated that the 2014 Edition QMS criterion was a first step that could be built on in an incremental fashion (77 FR 54191). For the 2015 Edition QMS criterion, we are taking that next step by *not* permitting health IT to be certified that has not been subject to a QMS and also requiring health IT developers to either use a recognized QMS or illustrate how the QMS they used maps to one or more QMS established by the federal government or a standards developing organization(s) (SDOs). As identified in the 2014 Edition final rule (77 FR 54190), QMS established by the federal government and SDOs include FDA's quality system regulation in 21 CFR part 820, ISO 9001, ISO 14971, ISO 13485, and IEC 62304. We encourage health IT developers to choose an established QMS, but developers are not required to do so, and may use either a modified version of an established QMS, or an entirely ''home grown'' QMS. In cases where a health IT developer does not use a QMS established by the federal government or an SDO, the health IT developers must illustrate how their QMS maps to one or more QMS established by the federal government or SDO through documentation and explanation that links the components of their QMS to an established QMS and identifies any gaps in their QMS as compared to an established QMS. We clarify that we have no expectation that there will be detailed documentation of historical QMS or their absence. The documentation of the current status of QMS in a health IT development organization would be sufficient.

We propose that all Health IT Modules certified to the 2015 Edition would need to be certified to the 2015 Edition QMS criterion. As such, we propose to revise § 170.550 to require ONC–ACBs follow this proposed approach (please see section IV.C.2 of this preamble for this proposal).

• *Accessibility Technology Compatibility*

2015 Edition Health IT Certification Criterion
§ 170.315(g)(5) (Accessibility technology compatibility)

We propose to adopt a new 2015 Edition ''accessibility technology compatibility'' certification criterion that would offer health IT developers that present a Health IT Module for certification to one or more certification criteria listed in proposed § 170.315(a), (b), or (e) the opportunity to have their health IT demonstrate compatibility with at least one accessibility technology for the user-facing capabilities included in the referenced criteria.

In response to the Voluntary Edition proposed rule, we received several comments from health IT users with visual impairments or disabilities. These commenters raised concerns about the lack of accessibility in many health IT products certified under the ONC Health IT Certification Program. Commenters suggested a number of ways in which the certification program could be leveraged to ensure that health IT is accessible to visually impaired and disabled individuals. In particular, many commenters strongly recommended that we require as a condition of certification that health IT be compatible with popular text-to-speech (or ''screen reader'') applications and other accessibility technologies.

Joined by our colleagues in the Administration for Community Living and Aging Policy and the Office for Civil Rights, we believe that health IT should be accessible to users regardless of their visual impairments or disabilities. The lack of accessibility features in health IT, including the lack of compatibility with third-party accessibility technologies, can place a significant burden on health IT users who are visually impaired or disabled. Without these features, some health IT users may be unable to access the health IT capabilities they and their patients

need. Other health IT users may be forced to rely on human intermediaries, revert to paper-based processes, or employ other workarounds in order to perform basic clinical tasks and essential aspects of their jobs. Such limitations and workarounds not only impact the autonomy, productivity, and employment opportunities of health IT users, but also jeopardize patient safety, healthcare quality, and efficiency. For example, without the use of appropriate accessibility technology, there may be an increased risk of transcription errors, miscommunication between clinicians, improperly documented patient health information, and untimely retrieval of patient health information. For these reasons, we strongly encourage health IT developers to consider the needs of visually impaired and disabled users when designing their products, and, where feasible, to integrate accessibility features directly into health IT. We also encourage them to seek certification to this proposed certification criterion.

We note that a number of text-to-speech applications exist and are widely used by many visually impaired or otherwise disabled individuals in conjunction with a variety of personal computer and mobile applications that lack built-in accessibility features. Text-to-speech applications may also be combined with voice control software and other accessibility technologies and typically provide a scripting language and/or set of APIs that enable third-party developers to leverage the accessibility technology's accessibility features in their own software applications. We have also observed that some health IT is already compatible with accessibility technology, including the U.S. Department of Veterans Affairs' Computerized Patient Record System (CPRS). CPRS is compatible with Job Access With Speech (JAWS), a popular text-to-speech application that enables a computer to verbally describe the controls and content of computer applications.

Certification to this proposed criterion would be available (not required) for Health IT Modules presented for certification to any of the clinical, care coordination, and patient engagement certification criteria specified at § 170.315(a), (b), and (e), respectively, because the use of capabilities associated with these criteria necessarily requires that a user provide input into, receive feedback from, or otherwise interact with the Health IT Module. To meet this proposed certification criterion, for each such ''user-facing'' capability included in certification criteria specified at § 170.315(a), (b), and (e), a Health IT Module would need to demonstrate that the capability is *compatible* with at least one accessibility technology that provides text-to-speech functionality to meet this criterion. Health IT developers would not be required to license or provide such accessibility technology to users in order to meet the criterion. An accessibility technology used to meet this criterion would also *not* be ''relied upon'' for purposes of § 170.523(f). However, it would need to be identified in the issued test report and would ultimately be made publicly available as part of the information ONC–ACBs are required to report to ONC for inclusion on the CHPL (in this case, what was used to demonstrate compliance with this certification criterion) so that users would be able to identify the accessibility technology with which the certified Health IT Module demonstrated its compatibility.

We note that all recipients of federal financial assistance from HHS are covered by the requirements of Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) for programs and services receiving federal financial assistance. We seek comment on the extent to which certification to this criterion would assist in complying with this and other applicable federal (*e.g.,* Section 508 of the Rehabilitation Act of 1973) and state disability laws. We also seek comment on whether certification to this criterion *as proposed* would serve as a valuable market distinction for health IT developers and consumers (*e.g.,* ''Health IT Module with certified accessibility features'').

• *Consolidated CDA Creation Performance*

2015 Edition Health IT Certification Criterion
§ 170.315(g)(6) (Consolidated CDA creation performance)

In the Voluntary Edition proposed rule (79 FR 10899), we proposed to adopt as part of the transitions of care certification criterion a new ''performance standard'' at § 170.212. This performance standard would have required health IT to be able to receive no less than 95% of all of the possible variations that could be implemented under the C–CDA. We summarized in the 2014 Edition Release 2 final rule (79 FR 54459) that commenters voiced concerns about the testability and vagueness of this proposed requirement, questioned its likelihood of success, and noted that the 95% threshold would be impractical, time consuming, and expensive to implement given the wide variation in C–CDA implementation. Ultimately, we did not finalize this proposal in the 2014 Edition Release 2 final rule.

As we considered these comments and reviewed the additional public dialogue surrounding the variability in the C–CDA's implementation by different health IT developers,[177] we concluded that a new certification criterion, focused principally on health IT system behavior and performance related to C–CDA creation was warranted. Thus, we propose to adopt a new certification criterion at § 170.315(g)(6) that would rigorously assess a product's C–CDA creation performance (for both C–CDA Release 1.1 and 2.0) when it is presented for a Health IT Module certification that includes within its scope any of the proposed certification criteria that require C–CDA creation (*e.g.,* § 170.315(b)(2)).

To implement this proposal, we also propose to amend § 170.550 to add a requirement that ONC–ACBs shall *not* issue a Health IT Module certification to a product that includes C–CDA creation capabilities within its scope, unless the product was also tested and satisfied the certification criteria requirements proposed at § 170.315(g)(6) (see also section IV.C.2 of this preamble for further discussion of this proposal). If the scope of certification sought includes multiple certification criteria that require C–CDA creation, § 170.315(g)(6) need only be tested in association with one of those certification criteria and would not be expected or required to be tested for each. We base this certification efficiency on assumption that passing this proposed certification criterion for one of the certification criteria that includes C–CDA creation will cause a health IT developer to apply these same performance checks to all other capabilities that include C–CDA creation. However, we request public comment on whether this proposed efficiency is desirable or would have any adverse consequences.

We propose that the C–CDA creation performance certification criterion would focus on and require the following technical outcomes to be met:

1. *Reference C–CDA Match:* the Health IT Module must demonstrate that it can create a C–CDA that matches a gold standard, called a Reference C–CDA. Reference C–CDAs would include the 2014 and 2015 edition data elements coded according to the HL7 C–CDA standards and regulatory requirements (the scope of the data would be limited

[177] D'Amore JD, et al. J Am Med Inform Assoc 2014; 21:1060-1068.

to what is proposed for the Common Clinical Data Set definition). As part of the Reference C–CDA Match, health IT developers would be provided test data that includes the 2014 and 2015 data elements and any context specific coding instructions to be used by Health IT Module to create C–CDA documents. The C–CDA documents created by the Health IT Module would be validated by comparing it to a Reference C–CDA.

2. *Document Template Conformance:* the Health IT Module must demonstrate that it can create C–CDA documents for the following C–CDA document templates as applicable to the C–CDA 1.1 and C–CDA 2.0 standards: CCD; Consultation Note; History and Physical; Progress Note; Care Plan; Transfer Summary; Referral Note; and for the inpatient setting only, Discharge Summary. We do not propose require as part of this portion of the certification criterion to require testing to the Diagnostic Imaging Report (DIR); Operative Note; and Procedure Note as they would not be generally applicable to all products.

3. *Vocabulary Conformance:* the Health IT Module must demonstrate that it can create C–CDA documents using the vocabularies and value sets adopted by the 2014 and 2015 edition. For data elements which do not require specific vocabularies and value sets in the regulation, the Health IT Module must use the vocabularies and value sets as specified in the C–CDA standard.

Additionally, in response to wide stakeholder feedback for additional publicly available C–CDA samples, we have coordinated with our colleagues at NIST and understand that NVLAP-Accredited Testing Laboratories would retain the C–CDA files created under test and contribute them to an ONC-maintained repository.

Completeness of Data in the C–CDA

Past feedback from providers has indicated that the variability associated with different functionalities and workflows within health IT can ultimately affect the completeness of the data included in a created C–CDA. Thus, in the same context associated with our proposals in this criterion and the ToC performance certification criterion, we are considering, and request public comment on, adding to either of these certification criteria an additional requirement that would evaluate the completeness of the data included in a C–CDA in order to ensure that the data recorded by health IT is equivalent to the data included in a created C–CDA.

• *Application Access to Common Clinical Data Set*

2015 Edition Health IT Certification Criterion

§ 170.315(g)(7) (Application access to Common Clinical Data Set)

We propose to adopt a new certification criterion as part of the proposed 2015 Edition at § 170.315(g)(7) that would focus on the capability of health IT presented for certification to respond to requests for patient data from other applications.[178] We propose that this certification criterion would require the demonstration of an application programming interface (API) that responds to data requests for any one or more of the data referenced in the Common Clinical Data Set definition (proposed for adoption at § 170.102), including requests for all of the data referenced in the Common Clinical Data Set.

The expanded access to a common data set from other applications through APIs (and other techniques) has been referenced in numerous publications over the past several years.[179] We have also received requests from stakeholders to include a certification requirement for the proposed capability. These stakeholders indicate that such a requirement would help promote innovation and enhance the ease with which health care providers could adopt and use third party software tools along with their core EHR technology to improve patient care.

For the purposes of this certification criterion, we also propose to require that this certification criterion be part of the set of criteria necessary to satisfy the ''2015 Edition Base EHR'' definition (see also section III.B.1 of this preamble for a discussion of the proposed 2015 Edition Base EHR definition). This additional proposal, due to its linkage to the CEHRT definition, would ensure that all EPs, eligible hospitals, and CAHs would need to adopt a Health IT Module certified to this criterion in order to have the necessary health IT to successfully demonstrate meaningful use under the EHR Incentive Programs.

With limited exceptions, we have broadly specified the technical outcomes required by this certification criterion. We have taken this approach in order to allow for a wide array of implementations to meet the certification criterion. The proposed certification criterion includes three technical outcomes and a documentation requirement.

(1) *Security.* The API needs to include a means for the establishment of a trusted connection with the application that requests patient data. This would need to include a means for the requesting application to register with the data source, be authorized to request data, and log all interactions between the application and the data source.

(2) *Patient Selection.* The API would need to include a means for the application to query for an ID or other token of a patient's record in order to subsequently execute data requests for that record.

(3) *Data requests, response scope, and return format.* The API would need to support two types of data requests and responses: ''by data category'' and ''all.'' In both cases, while the scope required for certification is limited to the data specified in the Common Clinical Data Set, additional data is permitted and encouraged.

• For ''data category'' requests, the API would need to respond to requests for each of the data categories specified in the Common Clinical Data Set (according to the specified standards, where applicable) and return the full set of data for that data category. As the return format, either XML or JSON would need to be produced. For example, an API function to request ''medications'' from patient 123456 that returns all of a patient's medications in XML or JSON would meet certification requirements.

• For ''all'' requests, the API would need to respond to requests for all of the data categories specified in the Common Clinical Data Set at one time (according to the specified standards, where applicable). As the return format, the C–CDA version 2.0 would need to be used to produce a patient summary record populated with the data included in the Common Clinical Data Set. For example, an API function to request the full common data set ''all'' from patient 567890 would return a patient's fully populated summary record formatted in accordance with the C–CDA version 2.0.

We believe the proposed approach provides ample flexibility for health IT developers to implement an API that can best address their customers' needs. It also leverages current standards that most health IT developers would

[178] We intend for the term ''application'' to generally encompass any other type of system or software that is not the data source responding to the requests for data.

[179] See: (1) President's Council of Advisors on Science and Technology (PCAST) ''Realizing the full potential of health information technology to improve healthcare for Americans: the path forward (December 2010)'';

(2) JASON: A Robust Health Data Infrastructure (April 2014);

(3) PCAST ''Better health care and lower costs: accelerating improvement through systems engineering (May 2014); and

(4) ONC ''Connecting Health and Care for the Nation: A 10-Year Vision to Achieve an Interoperable Health IT Infrastructure (June 2014).

already need to develop their products to support in order to seek certification to several other certification criteria. In addition, we believe that this approach supports future, innovative approaches to be used. The intent behind this certification criterion is to allow for, but not require, health IT developers to implement the Fast Health Interoperability Resource (FHIR®) REST API and accompanying FHIR standard specifications.[180] Therefore, if we have not adequately specified this certification criterion in a manner that accomplishes this goal, we solicit public comment on any specific revisions that would.

This certification criterion would require that the API be technically well documented and include its terms of use. It would also require that such technical documentation and the terms of use be submitted as part of testing for this certification criterion and subsequently to ONC–ACBs for review prior to issuing a certification. The technical documentation would need to include, at a minimum: API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns. The terms of use would need to include information of the API's developer policies and required developer agreements so that third party developers could assess these additional requirements before engaging in any development against the API. Similar to how we approached the submission of publicly available test results in our past rulemaking, we propose to require ONC–ACBs to submit a hyperlink (as part of its product certification submission to the CHPL) that would allow any interested party to access the API's documentation and terms of use. This hyperlink would need to be provided by the health IT developer to the ONC–ACB.

With respect to testing for this certification criterion, we expect that functional testing would focus primarily on the third capability we propose. Meaning that for each function call made the health IT developer would need to demonstrate to/show an Accredited Testing Lab the response (*i.e.,* output) for each of the data category requests in JSON or XML and for the ''all'' request, the output according to the Consolidated CDA. For all other aspects of the certification criterion, we expect the testing would include attestation, documentation, and review. Additionally, if these capabilities do not function properly when implemented in the field, the (at that point) certified Health IT Module could be subject to surveillance by its ONC–ACB.

The HITPC called for ''well-defined, fairly applied, business and legal frameworks for using the API.'' [181] We request public comment on what additional requirements might be needed to ensure the fostering of an open ecosystem around APIs so that patients can share their information with the tools, applications, and platforms of their own choosing. For instance, should there be any limits expressed on what can be included in the terms of use? Should the terms be required to more granularly address security and authorization requirements, for instance by requiring a certain oAuth profile?

We also request public comment regarding the feasibility of additional API capabilities that could be made available to certification including secure message read/write capability, schedule read/write capability, ordering/e-prescribing capability, and task list read/write capability.

C–CDA Creation Capability Request for Comment

We request public comment on a potential means to provide explicit implementation clarity and consistency as well as to further limit potential burdens on health IT developers. Specifically, should we limit the scope of C–CDA creation capability within this certification criterion to focus solely on the creation of a CCD document template based on the C–CDA Release 2.0? This approach could also have the benefit of creating clear expectations and predictability for other health IT developers who would then know the specific document template implemented for compliance with this criterion.

- *Accessibility-Centered Design*

2015 Edition EHR Certification Criterion
§ 170.315(g)(8) (Accessibility-centered design)

We propose to adopt a new 2015 Edition ''accessibility-centered design'' certification criterion that would apply to all Health IT Modules certified to the 2015 Edition. This criterion would require the identification of user-centered design standard(s) or laws for accessibility that were applied, or complied with, in the development of specific capabilities included in a Health IT Module or, alternatively, the lack of such application or compliance.

This proposed certification criterion would serve to increase transparency around the application of user-centered design standards for accessibility to health IT and the compliance of health IT with accessibility laws. We believe this transparency would be beneficial for those health care providers, consumers, governments, and other stakeholders that have an interest in knowing the degree to which heath IT, particularly certified health IT, meet health IT accessibility standards and laws. This transparency may also encourage health IT developers to pursue the application of more accessibility standards and laws in product development that could lead to improved usability for health care providers with disabilities and health care outcomes for patients with disabilities.

We propose to model our approach and this criterion after the 2014 Edition ''quality management system'' criterion (§ 170.314(g)(4) and see 77 FR 54270–54271). Therefore, as a first step, for each capability that a Health IT Module includes and for which that capability's certification is sought, the use of a health IT accessibility-centered design standard or compliance with a health IT accessibility law in the development, testing, implementation, and maintenance of that capability must be identified. Working with our colleagues at NIST, we have identified an initial list of health IT accessibility-centered design standards and accessibility laws below. However, health IT developers may choose to use other health IT accessibility standards or laws in the development, testing, implementation, and maintenance of capabilities, but must identify these standards and/or laws for the purposes of certification. As with the 2014 Edition ''quality management system'' criterion, we propose to permit a response that ''no health IT accessibility-centered design standard or law was applied to all applicable capabilities'' as an acceptable means of satisfy this proposed certification criterion. We note, however, that whatever method(s) is used to meet this proposed criterion, it would be reported to the proposed open data CHPL.

We solicit comments on whether the standards and laws identified below are appropriate examples and whether we should limit the certification criteria to which this criterion would apply. For example, limiting it to a Health IT Module certified only to the certification criteria proposed in § 170.315(a), (b), (c), and (e), or

[180] *http://www.hl7.org/implement/standards/fhir/.*

[181] *http://www.healthit.gov/sites/faca/files/JTF_Transmittal%20Letter_2014-1-22-15v3.pdf.*

otherwise. To note, we believe that, at a minimum, this criterion would not apply to the certification criteria in § 170.315(g).

Example health IT accessibility-centered design standards and accessibility laws:

- ETSI ES 202 076—Human Factors (HF); User Interfaces; Generic spoken command vocabulary for ICT devices and services;
- ETSI ETS 300 679—Terminal equipment (TE); Telephony for the hearing impaired; Electrical coupling of telephone sets to hearing aids;
- ETSI TR 102 068 (2002) Human Factors (HF): Requirements for assistive technology devices in ICT;
- ETSI TS 102 511 (2007) Human Factors (HF): AT commands for assistive mobile device interfaces;
- IEEE 802.11 IEEE standard for Information Technology; Telecommunications and information: Exchange between systems; local and metropolitan area network; specific requirements—Part 11: Wireless LAN Medium Access Control (MAC) and Physical Layer (PHY) Specification;
- ISO 13406–1 (1999) Ergonomic requirements for work with visual displays based on flat panels. Part 1—Introduction;
- ISO 13406–2 (2001) Ergonomic requirements for work with visual displays based on flat panels. Part 2—Ergonomic requirements for flat panel displays;
- IEC 80416–1 (2001) Basic principles for graphical symbols for use on equipment—Part 1: Creation of symbol originals;
- ISO 80416–2 (2002) Basic principles for graphical symbols for use on equipment—Part 2: Form and use of arrows;
- IEC 80416–3 (2002) Basic principles for graphical symbols for use on equipment—Part 3: Guidelines for the application of graphical symbols;
- ISO 80416–4 (2005) Basic principles for graphical symbols for use on equipment. Part 4—Guidelines for the adaptation of graphical symbols for use on screens and displays;
- ISO 9241–151 (2008) Ergonomics of human-system interaction—Part 151: Guidance on World Wide Web user interfaces;
- ISO 9355–1 (1999) Ergonomic requirements for the design of displays and control actuators. Part 1: Human interactions with displays and control actuators;
- ISO 9355–2 (1999) Ergonomic requirements for the design of displays and control actuators. Part 2: Displays;
- ISO 9999 (2007) Assistive products for persons with disability—Classification and terminology;
- ISO/CD 24500 Guidelines for all people, including elderly persons and persons with disabilities—Auditory signals on consumer products;
- ISO/IEC 15411 (1999) Information technology—Segmented keyboard layouts;
- ISO/IEC 15412 (1999) Information technology—Portable keyboard layouts;
- ISO/IEC 24755 (2007) Information technology—Screen icons and symbols for personal mobile communication devices;
- ISO/IEC CD 24786–1 Information Technology—User interfaces—Accessible user interface for accessibility setting on information devices—Part 1: General and methods to start;
- ISO/IEC TR 15440 (2005) Information Technology—Future keyboards and other associated input devices and related entry methods;
- ISO/IEC TR 19765 (2007) Information technology—Survey of icons and symbols that provide access to functions and facilities to improve the use of IT products by the elderly and persons with disabilities;
- ISO/IEC TR 19766 (2007) Information technology—Guidelines for the design of icons and symbols accessible to all users, including the elderly and persons with disabilities;
- ITU–T E.902 (1995) Interactive services design guidelines;
- ITU–T P.85 (1994) A method for subjective performance assessment of the quality of speech voice;
- Section 504 of the Rehabilitation Act; and
- Section 508 of the Rehabilitation Act.

Because we propose that Health IT Modules certified to the 2015 Edition would be required to be certified to the 2015 Edition Accessibility-centered design criterion, we also propose to revise § 170.550 to require ONC–ACBs follow this proposed approach (please see section IV.C.2 of this preamble for this proposal).

- *Transport Methods and Other Protocols*

We propose two ways for providers to meet the 2015 Edition Base EHR definition using health IT certified to transport methods. These ways serve to account for transport methods that we understand are being used to readily exchange electronic health information and ensure that providers have interoperable ways to exchange electronic health information. The first way to meet the proposed 2015 Edition Base EHR definition requirement would be for a provider to have health IT certified to § 170.315(b)(1) and (h)(1) (Direct Project specification). This would account for situation where a provider uses a health IT developer's product that acts as the ''edge'' *and* the HISP. The second way would be for a provider to have health IT certified to § 170.315(b)(1) (ToC criterion) and (h)(2) (Direct Project, Edge Protocol, and XDR/XDM). This would account for situations where a provider is using one health IT developer's product that serves as the ''edge'' and another health IT developer's product that serves as a HISP.[182] The capabilities included in proposed § 170.315(h)(2) ensure interoperability by accounting for various electronic health information exchange options using the Direct Project specification. To fully implement this approach, we propose to revise § 170.550 to require an ONC–ACB to ensure that a Health IT Module includes the certification criterion adopted at § 170.315(b)(1) in its certification's scope in order to be certified to the certification criterion proposed for adoption at § 170.315(h)(1). We welcome comment on these proposed approaches and the transport standards listed below in § 170.315(h)(1) through (3).

Consistent with our proposed title of ''transport methods and other protocols'' for § 170.315(h), we proposed to revise the heading of § 170.202 from ''transport standards'' to ''transport standards and other protocols.''

- *Direct Project*

2015 Edition Health IT Certification Criterion
§ 170.315(h)(1) (Direct Project)

We propose to adopt a certification criterion that includes the capability to send and receive according to the Applicability Statement for Secure Health Transport (the primary Direct Project specification) adopted at § 170.202(a). We previously adopted this capability for the 2014 Edition at § 170.314(b)(1), (b)(2) and (h)(1). We remind health IT developers that best practices exist for the sharing of electronic health information and enabling the broadest participation in electronic health information exchange with Direct.[183]

We propose to include as an optional capability for certification, the capability to send and receive according to the Implementation Guide for Delivery Notification in Direct, Version 1.0, June 29, 2012, which we propose to

[182] See the 2014 Edition Release 2 final rule for more discussion on such situations (79 FR 54436–38).

[183] *http://wiki.directproject.org/Best+Practices+for+Content+and+Workflow.*

adopt at § 170.202(e). While this is not a capability we have previously adopted, we proposed to adopt it as part of the Voluntary Edition proposed rule (79 FR 10914). The primary Direct Project specification requires that Security/Trust Agents (STAs) must issue a Message Disposition Notification (MDN, RFC3798) with a disposition of processed upon successful receipt, decryption, and trust validation of a Direct message. By sending this MDN, the receiving STA is taking custodianship of the message and is indicating that it will deliver the message to its destination. While the primary Direct Project specification indicates that additional MDNs may be sent to indicate further processing progress of the message, they are not required. The primary Direct Project specification, however, does *not* provide guidance in regards to the actions that should be taken by the sending STA in the event an MDN processed message is not received or if the receiving STA cannot deliver the message to its destination after sending the initial MDN processed message. Due to the lack of specifications and guidance in the primary Direct Project specification regarding deviations from normal message flow, STAs implementing only requirements denoted as ''must'' in Section 3 of the primary Direct Project specification may not be able to provide a high level of assurance that a message has arrived at its destination. The Delivery Notification IG provides implementation guidance enabling STAs to provide a high level of assurance that a message has arrived at its destination and outlines the various exception flows that result in compromised message delivery and the mitigation actions that should be taken by STAs to provide success and failure notifications to the sending system.

Based on CMS guidance, the use of the Delivery Notification IG can be used to provide the necessary level of assurance that sent laboratory results are received by a provider.[184] Additionally, we note that the Delivery Notification IG could be generally useful for any transmission that requires a high level of assurance.

• *Direct Project, Edge Protocol, and XDR/XDM*

2015 Edition Health IT Certification Criterion

§ 170.315(h)(2) (Direct Project, Edge Protocol, and XDR/XDM)

We propose to include three distinct capabilities in this criterion. The first capability is the capability to send and receive according to the Applicability Statement for Secure Health Transport (the primary Direct Project specification) adopted at § 170.202(a). The second capability is to send and receive according to both Edge Protocol methods specified by the standard adopted at § 170.202(d). The third capability is to send and receive according to the XDR and XDM for Direct Messaging Specification adopted at § 170.202(b). These three capabilities were previously adopted as part the 2014 Edition, including through the 2014 Edition and 2014 Edition Release 2 final rules. We remind health IT developers that best practices exist for the sharing of information and enabling the broadest participation in information exchange with Direct.[185]

• *SOAP Transport and Security Specification and XDR/XDM for Direct Messaging*

2015 Edition Health IT Certification Criterion

§ 170.315(h)(3) (SOAP Transport and Security Specification and XDR/XDM for Direct Messaging)

We propose to adopt a 2015 Edition certification criterion for electronic transmission that would include the capability to send and receive according to the Transport and Security Specification (also referred to as the SOAP-Based Secure Transport RTM adopted at § 170.202(c)) and its companion specification XDR and XDM for Direct Messaging Specification adopted at § 170.202(b) We previously adopted this capability for the 2014 Edition at § 170.314(b)(1), (b)(2) and (h)(3).

• *Healthcare Provider Directory—Query Request*

2015 Edition Health IT Certification Criterion

§ 170.315(h)(4) (Healthcare Provider Directory—query request)

In June 2011, the HITPC recommended[186] that we consider the adoption of provider directory capabilities for the ONC Health IT Certification Program as well as work to address many of the issues they raised. To address the HITPC's recommendations, ONC launched a number of initiatives to define a single provider directory standard and to pilot its use.

ONC worked with implementers and subject matter experts in the field to hone in on the specific types of capabilities that should be included in a provider directory criterion. Stakeholders voiced a desire for technology to have the ability to be able to query individual directory sources and directory sources federated by third parties such as HIOs, RHIOs, HISPs etc. This is also known as ''federated querying.'' However, there were only a few implementations of federated querying across the country and many were unique due to the lack of a single standard. Given this challenge, and its potential to inhibit exchange, ONC launched an open source project called ''Modular Specification Provider Directories (MSPD).''[187]

During the MSPD project, stakeholders collaborated to identify requirements for an updated version of the ''Healthcare Provider Directory (HPD)'' profile in order to provide a unified vendor-neutral platform for implementation of provider directories that supports both federated and non-federated architectures. The project resulted in implementable, testable specifications, and high quality test cases that verify conformance to the ''test implementation'' and it is now part of an approved IHE HPD profile Change Proposal[188]. In addition, ONC awarded a grant to the EHR |√ HIE Interoperability Workgroup[189] to pilot provider directory standards with multiple states.

The original HPD profile created by Integrating the Healthcare Enterprise (IHE)[190] addresses transactions between the client and a single provider directory with a single data source. While the standard can be used for federation, it does not address the complexities introduced by federation; provide a well-defined and straightforward approach to error handling; support targeted queries to federated data sources; or define mechanisms by which to distinguish the source of results in a given response. IHE (in collaboration with ONC, eHealth Exchange and the EHR | HIE Interoperability Work Group) has

[184] See CMS CLIA guidance on the use of Direct with the Delivery Notification IG: *http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/Survey-and-Cert-Letter-14-05.html?DLPage=1&DLFilter=2014&DLSort=3&DLSortDir=ascending.*

[185] *http://wiki.directproject.org/Best+Practices+for+Content+and+Workflow.*

[186] *http://www.healthit.gov/sites/default/files/pdf/HITPC_transmit_InfoExchWG_May2011-final signed.pdf.*

[187] *http://modularspecs.siframework.org/Provider+Directories+Homepage.*

[188] *ftp://ftp.ihe.net/IT_Infrastructure/TF_Maintenance-2015/CPs/3_FinalText/from_Ballot_24/CP-ITI-792-05.doc.*

[189] *http://www.interopwg.org/.*

[190] *http://wiki.ihe.net/index.php?title=Healthcare_Provider_Directory.*

worked to update the IHE HPD profile to address federation. In September of 2013 ONC submitted a change proposal to IHE to incorporate the MSPD IG into the HPD profile. Through the IHE balloting process modifications were made to the change proposal to be backwards compatible with the existing IHE HPD Profile. These changes were implemented by multiple organizations to prove the feasibility and ease of implementation of the change proposal. This revised change proposal was approved by IHE in September 2014.[191] In August 2013, the HITPC recommended including a provider directory standard in the EHR Incentive Programs Stage 3.[192] The Voluntary Edition proposed rule included a request for public comment on a potential future ''provider directory'' certification criterion that would, ''at a minimum,'' require health IT to be able to query provider directories for the following information and electronically process the response returned in accordance with the IHE HPD profile requirements

- Query for an individual provider;
- Query for an organizational provider; and
- Query for relationships between individual providers and organizational providers.

We received twenty-three comments related to the provide directory question. Twenty of those comments were supportive of the inclusion of a provider directory standard in the 2015 Edition. In July 2014, the HITSC released their analysis on the IHE HPD profile, stating that the IHE HPD+ profile[193] was a good start, but not yet mature enough for nationwide implementation.[194]

Based on the feedback we received from stakeholders on the Voluntary Edition proposed rule recommending the adoption of IHE HPD and the results of pilots undertaken by EHR | HIE Interoperability Workgroup and others, we believe that making the IHE HPD profile available for testing and certification would benefit its further use and implementation in the field. Therefore, we propose a new certification criterion that would require a Health IT Module to be capable of querying a directory using the IHE HPD Profile.[195] In addition, we propose including an optional capability within this certification criterion that addresses federated requirements. In this optional capability, we propose that the Health IT Module would be required to follow the approved federation option of IHE HPD[196] to accomplish querying in federated environments. The federation change proposal was approved in September, 2014 and was incorporated into the IHE HPD Profile.[197] While the IHE HPD profile provides the ability to perform queries about individual providers, organizational providers, provider credentials and other details about providers, this proposed certification criterion seeks to establish a minimum set of queries that a Health IT Module would be required to support. The capabilities that would need to be supported by a Health IT Module include: (1) Querying for an individual provider; (2) Querying for an organizational provider; (3) Querying for both individual and organizational provider in a single query; (4) Querying for relationships between individual and organizational providers; and (5) electronically processing the response according to the IHE HPD Profile.

We believe making this basic infrastructure component available for testing and certification could assist EPs, EHs, and CAHs in achieving the ToC requirements under the EHR Incentive Programs by enabling them to find electronic service information such as Direct addresses for providers who participate in other HISPs/HIEs. It would also drive a common approach to directories across trust communities, which would improve interoperability across these communities.

- *Healthcare Provider Directory—Query Response*

2015 Edition Health IT Certification Criterion
§ 170.315(h)(5) (Healthcare Provider Directory—query response)

To complement the certification criterion we propose for adoption at 170.315(h)(4) related to health IT issuing a ''query request,'' we also propose to adopt a certification criterion at 170.315(h)(5) that would focus on the ''query response'' and include the corresponding set of capabilities to respond to a provider directory query. This proposed separation would provide developers with the flexibility to test and certify for provider directory ''query'' independent of the provider directory ''response.'' A health IT system would be able to be presented for testing and certification to both proposed certification criteria if applicable or just to one or the other as appropriate based on the product's capabilities.

Health IT systems serving as ''directory sources'' that would be seeking testing and certification to (h)(5) would have to support responding to the same queries initiated by systems seeking testing and certification to (h)(4) for interoperability purposes. As part of this proposed certification criterion, we propose that directory sources must demonstrate the capability to respond to provider directory queries according to the IHE HPD profile. Additionally, as part of the certification criteria, we propose that the directory sources must respond to the following provider directory queries

- Query for an individual provider;
- Query for an organizational provider; and
- Query for relationships between individual providers and organizational providers.

In addition we propose including an optional capability within this certification criterion to address federated requirements. In this optional capability, we propose that the Health IT Module would be required to follow the approved federation option of for IHE HPD to accomplish querying in federated environments. The federation change proposal was approved in September, 2014 was incorporated into the IHE HPD Profile.

- *Electronic Submission of Medical Documentation*

2015 Edition Health IT Certification Criterion
§ 170.315(i)(1) (Electronic submission of medical documentation)

We propose to adopt a new certification criterion as part of the proposed 2015 Edition at § 170.315(i)(1) that would focus on the electronic submission of medical documentation.

According to CMS, the Medicare Fee for Service (FFS) program currently spends in excess of $360 billion annually to provide services to over 35 million beneficiaries (excludes Medicare eligible individuals enrolled in non-FFS Medicare Programs).[198] The 2013 CMS Office of Financial Management (OFM) Improper Payment

[191] *ftp://ftp.ihe.net/IT_Infrastructure/TF_Maintenance-2015/CPs/3_FinalText/from_Ballot_24/CP–ITI–792–05.doc.*

[192] *http://www.healthit.gov/FACAS/sites/faca/files/IE%20WG_Recommendation%20Transmittal_MU3v2.docx.*

[193] *http://ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_HPD_Rev1.4_TI_2013-09-20.pdf.*

[194] *http://www.healthit.gov/FACAS/sites/faca/files/HITSC_NwHIN_Provider_Directory_2014-07-16.pdf.*

[195] *http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_HPD.pdf.*

[196] *http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_HPD.pdf.*

[197] *http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_HPD.pdf.*

[198] *http://www.hhs.gov/budget/fy2015/fy-2015-budget-in-brief.pdf.*

Report [199] noted that 12.7% (or $45.8 B) of the payments from the Medicare trust fund were for claims for services that were either: 1) not medically necessary and appropriate based on documentation that was submitted; or 2) insufficiently documented to determine if the billed service was necessary.

To respond to Congress' mandate [200] to more effectively manage improper payments, while recognizing the importance of reducing administrative burden for providers, CMS OFM's Provider Compliance Group (PCG) established the electronic submission of Medical Documentation (esMD) program to begin to enable the electronic submission of medical documentation.[201] As part of this program, CMS worked with ONC to establish the ''esMD Initiative'' under the S&I Framework.[202] This initiative created use cases and identified appropriate standards to facilitate the electronic exchange of medical documentation among providers and Medicare FFS review contractors. Currently, esMD Phase 1 supports the submission of unstructured data in PDF format. This method of submission is broadly deployed and accounts for over 25% of all Medicare FFS post-payment medical review submissions. In addition to post-payment review, new demonstration programs are focused on prior-authorization for specific services that have high improper payment rates. Prior-authorization ensures appropriate documentation is reviewed prior to these services/items being performed or delivered in order to avoid post-payment denials that may affect the beneficiary, the provider, or both.

In addition to current methods for submitting medical documentation (*e.g.,* mail, fax, PDF), Medicare FFS seeks to also enable a standardized and interoperable electronic approach that would reduce the time, expense, and paper required in current manual processes used for prior authorization, pre-payment review, post-payment audit, and quality management. Acceptable methods must ensure that providers are able to submit any documentation they believe is required in order to show that a proposed or provided service meets applicable requirements.

The esMD Initiative electronic Determination of Coverage (eDoC) workgroup provided an open forum for providers and payers to establish a mutual understanding of the requirements necessary for submission of structured medical documentation to support prior authorization, pre-payment review and post-payment audit. Standards analysis by the workgroup revealed a significant gap in the current standards with respect to uses that went beyond the exchange of a summary care record between providers. To address this gap, participants in the eDoC workgroup created a new Clinical Documents for Payers—Set 1 (CDP1) IG to further extend and constrain the C–CDA Release 2.0 standard.

Non-repudiation of signatures for electronic submission of medical documentation was a complementary challenge faced by the esMD Initiative. While keeping in mind the cost and impact of certain requirements, the esMD Initiative focused on two approaches to digital signatures. The ''Author of Record Level 1'' use case addressed the need for digital signatures on groups of documents and on single transactions. The ''Author of Record Level 2'' use case focused on digital signatures that could be embedded in HL7 CDA documents and included support for multiple signers where each declares their role and signature purpose. In addition to the ability to support digital signatures using industry standards, the use cases also addressed a standards-based method for the delegation, by a holder of a digital certificate, of the right to sign on their behalf by another holder of a digital certificate. While digital signatures have been implemented in the healthcare industry for other purposes, this effort will extend their use to declare and secure the provenance of single documents, bundles of documents, and transactions. The use of digital signatures on C–CDA documents will guarantee the identity of the author and ensure the integrity of the data once the document has been signed.

In summary, the esMD Initiative and its participants successfully produced standards and implementation guides to help minimize improper payments; improve interoperability for electronic submission of medical documentation, including parameters for non-repudiation, and reduce administrative burden associated with prior authorization, pre-payment review, post-payment audit and quality management.

In light of this work, we propose to adopt a certification criterion at § 170.315(i)(1) to support the electronic submission of medical documentation that includes four specific capabilities, which are each discussed in more detail below. As we mentioned in the Executive Summary of this proposed rule and discuss in more detail under section IV.B of this preamble (Modifications to the ONC Health IT Certification Program), we propose to broaden the scope of the ONC Health IT Certification Program beyond just focusing on supporting the EHR Incentive Programs. As such, we seek to make clear that this certification criterion is not within those programs' scope and is meant to be available to support other CMS program policy objectives as well as health care providers' ability to communicate encounter documentation to a payer, in particular to satisfy Medicare FFS coverage determination rules.

Capability 1—We propose that a Health IT Module be able to support the creation of a document in accordance with the HL7 Implementation Guide for CDA Release 2: Additional CDA R2 Templates—Clinical Documents for Payers—Set 1, Release 1—US Realm [203] in combination with the C–CDA Release 2.0 standard (proposed for adoption at § 170.205(a)(4)). We propose to adopt the most recent version of the CDP1 IG at § 170.205(a)(5)(i).[204] The CDP1 IG is designed to be used in conjunction with C–CDA Release 2.0 templates and makes it possible for providers to exchange a more comprehensive set of clinical information. For example, payers such as Medicare FFS allow providers to submit any information they believe substantiates that a service is medically necessary and appropriate under the applicable coverage determination rules.

A Health IT Module's support for the document-level templates formatted in accordance with the CDP1 IG would ensure that the technology is able to communicate all information relative to a patient encounter or assert that information for each ''required'' section is not available/included. If the provider then applies a digital signature to the document (as discussed in more detail below), the result is a non-repudiation

[199] *http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/index.html?redirect=/cert.*

[200] *http://www.whitehouse.gov/sites/default/files/omb/financial/_improper/PL_107–300.pdf*; *http://www.gpo.gov/fdsys/pkg/PLAW–112publ248/pdf/PLAW–112publ248.pdf*; and *www.whitehouse.gov/sites/default/files/omb/financial/_improper/PL_111-204.pdf.*

[201] *http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/ESMD/index.html?redirect=/ESMD.*

[202] *http://wiki.siframework.org/esMD+-+Charter+and+Members.*

[203] *http://www.hl7.org/special/Committees/claims/index.cfm.* We also note that access to the current draft of the CDP1 IG is freely available for review during the public comment period by establishing an HL7 user account.

[204] This would be the version of the IG (DSTU) that completes the ballot cycle before issuance of a subsequent final rule.

declaration of the encounter information.

The CDP1 IG was balloted in February of 2014 and should complete balloting this spring.[205] The February 2014 balloted version includes the following new templates:

(1) Five (5) new or additionally constrained document level templates:

- Enhanced Encounter Document
- Enhanced Hospitalization Document
- Enhanced Operative Note Document
- Enhanced Procedure Document
- Interval Document

(2) Four (4) new section level templates:

- Additional Documentation Section
- Externally Defined Clinical Data Elements Section
- Placed Orders Section
- Transportation Section

(3) Three (3) additionally constrained C–CDA Release 2.0 section level templates:

- Functional Status Section
- Plan of Treatment Section
- Social History Section

(4) New or additionally constrained entry level templates that provide support for new section level templates.

The most recent changes to the CDP1 IG include:

- Expanded descriptions regarding the use of the IG;
- References to and a list of additional constraints for templates that are based on the C–CDA Release 2.0 templates;
- Updates required for conformance with the published version of the C–CDA Release 2.0 ;
- Removal of attestation language and addition of a document succession description (clarification of standard C–CDA document succession);
- Technical corrections; and
- Name changes for the IG and the individual document level templates.

The CDP1 IG enables documentation to be completely and accurately conveyed in the new document templates. To do this, the document level templates referenced by the CDP1 IG require the inclusion of the referenced section level templates, which also include additional specificity and constraints. While a Health IT Module would need to support the entry of additional information, providers would not necessarily be required to collect any additional information to satisfy the new constraints. In other words, a specific nullFlavor may be used by the Health IT Module when creating the CDP1 IG document to indicate that no information is available for the relevant section or entry level template. Likewise, the Health IT Module may enable the provider to indicate that while information is present in the medical record it is not applicable to the purpose for which the document is intended and would subsequently result in an appropriate nullFlavor in the created CDP1 document.

To meet this capability included in the proposed certification criterion, a Health IT Module must be able to create a document that also conforms to the CDP1 IG's requirements along with appropriate use of nullFlavors to indicate when information is not available in the medical record for section or entry level template required in the CDP1 IG. In addition, a conformant Health IT Module must also demonstrate the ability to generate the document level templates as defined in the C–CDA Release 2.0, including the unstructured document.

We propose to further refine this certification criterion's scope relative to the applicable document templates within the C–CDA Release 2.0 and CDP1 IG that would need to be tested and certified for specific settings for which a Health IT Module is designed. Specifically, we propose that a Health IT Module:

- Would, regardless of the setting for which its designed, need to be tested and certified to the following document templates:
  - Diagnostic Imaging Report;
  - Unstructured Document;
  - Enhanced Operative Note Document;
  - Enhanced Procedure Note Document; and
  - Interval Document.
- Designed for the ambulatory setting would also need to be certified to the Enhanced Encounter Document.
- Designed for the inpatient setting would also need to be certified to Enhanced Hospitalization Document.

Capability 2—We propose that a Health IT Module be able to support the use of digital signatures embedded in C–CDA Release 2.0 and CDP1 IG documents templates by adopting the HL7 Implementation Guide for CDA Release 2: Digital Signatures and Delegation of Rights, Release 1 (DSDR IG) (proposed for adoption at § 170.205(a)(5)(ii)).[206] This DSDR IG defines a method to embed digital signatures in a CDA document and provides an optional method to specify delegation of right assertions that may be included with the digital signatures. We note, however, that for the purposes of certification, we propose to require that that optional method must be demonstrated to meet this certification criterion. The implementation of this IG will allow payers, such as Medicare, to accurately authenticate the authorized signers of CDA document and trust the validity and authenticity of signed medical documentation. The DSDR IG provides specific guidance on the use of digital signatures embedded in a CDA document to:

- Provide a non-repudiation signature that attests to the role and signature purpose of each authorized signer to the document.
- Provide for a delegation of rights where the signer is a delegated signer and not the authorized signer responsible individual or organization (*e.g.,* the signer is acting as an authorized agent).
- Define the method of incorporating multiple digital signatures and delegation of right assertions into the header of a CDA document.
- Define how to create the digest of the CDA document
- Define how to sign and incorporate the:
  - CDA digest;
  - Timestamp;
  - Role of the signer;
  - Purpose of signature.
- Define how to incorporate the:
  - The public certificate of the signer;
  - Long term validation data, including Online Certificate Status Protocol (OCSP) response and/or Certificate Revocation List (CRL).

Digital signatures ensure that the recipient of the signed document can authenticate the authorized signer's digital certificate, the signature artifact(s), determine the signer's role and signature purpose and validate the data integrity of the document. To create a valid digital signature that meets Federal Information Processing Standards (FIPS)[207], Federal Information Security Management Act of 2002 (FISMA)[208], and Federal Bridge Certification Authority (FBCA) requirements[209], the system used to digitally sign C–CDA Release 2.0 or CDP1 IG documents in accordance with

[205] *http://www.hl7.org/special/Committees/claims/index.cfm.* We also note that access to the current draft of the CDP1 IG is freely available for review during the public comment period by establishing an HL7 user account.

[206] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=375.*

[207] *http://www.nist.gov/itl/fips.cfm.*

[208] *http://csrc.nist.gov/drivers/documents/FISMA-final.pdf.*

[209] *http://www.idmanagement.gov/sites/default/files/documents/FBCA%20Certificate%20Policy%20v2.27.pdf.*

the DSDR IG must meet the following requirements:

(1) The cryptographic module [210] used must:

a. Be validated to meet or exceed FIPS 140–2, Level 1.

b. Implement a digital signature system and hash function must be compliant with FIPS 186–2 and FIPS 180–2.

c. Store the private key on a FIPS 140–2 Level 1 validated cryptographic module using a FIPS-approved encryption algorithm.

(2) The system must support multi-factor authentication that meets or exceeds Level 3 assurance as defined in NIST SP 800–63–2.

(3) The system must set a 10-minute inactivity time period after which the certificate holder must re-authenticate the password to access the private key.

(4) For software implementations, when the signing module is deactivated, the system must clear the plain text private key from the system memory to prevent the unauthorized access to, or use of, the private key.

(5) The system must have a time system that is synced with the official National Institute of Standards and Technology time source (as described by the standard adopted at 45 CFR 170.210(g)).

For the purposes of testing and certification, we propose that the first requirement (cryptographic module requirements) be met through compliance documentation. For all other specific capabilities in the list above, we expect testing and certification to assess the capabilities expressed.

We also propose that a Health IT Module must demonstrate the ability to validate a digital signature embedded in a C–CDA Release 2.0 document that is conformant with the DSDR IG. The requirements to perform this action are included in the DSDR IG.

Capability 3—We propose that a Health IT Module be able to support the creation and transmission of ''external digital signatures'' for documents. These digital signatures may be used to sign any document for the purpose of both data integrity and non-repudiation. The esMD Initiative defines the requirements in the Author of Record Level 1: Implementation Guide.[211] We propose to adopt this IG at § 170.205(a)(5)(iii). The Author of Record Level I IG uses the IHE DSG standard to provide a signer with the ability to digitally sign multiple documents and embed the W3C compliant XADES signature in a signature document that may accompany the signed documents or as a ''wrapper'' for the documents. This signing capability is intended for use when the sender of one or more documents needs to ensure that the transmitted documents include the non-repudiation identity of the sender and ensure that the recipient can validate that the document s have not been altered from the time of signing. This is not intended to replace the ability to embed multiple digital signatures in a C–CDA Release 2.0 and CDP1 IG document. The Author of Record Level 1 IG provides specific guidance on the use of a single digital signature, external to document, to:

- Provide a non-repudiation signature that attests to the identity of the signer;
- Allows the recipient to validate the data integrity of the signed document;
- Provide for a delegation of rights where the signer is a delegated signer and not the authorized signer responsible individual or organization (*e.g.,* the signer is acting as an authorized agent); and
- Defines how to incorporate the public certificate of the signer.

Digital signatures ensure that the recipient of the signed document can authenticate the authorized signer's digital certificate, the signature artifact(s), and validate the data integrity of the document. The system requirements in place to apply digital signatures on documents are the same as in capability 2 with the addition of a requirement that specifies that a Health IT Module must be able to digitally sign single or bundles of documents in conformance with the Author of Record Level 1 IG.

Capability 4—We propose that a Health IT Module be able to support the creation and transmission of digital signatures for electronic transactions for the purpose of both data integrity and non-repudiation authenticity. The esMD Initiative defines the requirements in the Provider Profiles Authentication: Registration Implementation Guide.[212] We propose to adopt this IG at § 170.205(a)(5)(iv). The Provider Profiles Authentication: Registration IG uses the W3C XADES digital signature standard to ''sign'' the contents of an electronic transaction and include the signature as accompanying metadata in the signed transaction. This signing capability is intended for use when the sender or recipient of a transaction needs to ensure that the transmitted information include the non-repudiation identity of the sender and ensure that the recipient can validate that the authenticity and integrity of the transaction information. This is not intended to replace the digital signature requirements defined in either Capability 2 or 3 above. The Provider Profiles Authentication: Registration IG provides specific guidance on the creation and use of a single digital signature for an electronic transaction, as accompanying metadata, to:

- Provide a non-repudiation signature that attests to the identity of the signer;
- Allow the recipient to validate the data integrity of the signed transaction;
- Provide for a delegation of rights where the signer is a delegated signer and not the authorized signer responsible individual or organization (*e.g.,* the signer is acting as an authorized agent); and
- Define how to incorporate the public certificate of the signer.

Digital signatures ensure that the recipient of the signed transaction can authenticate the authorized signer's digital certificate, the signature artifact(s), and validate the data integrity of the transaction. The system requirements in place to apply digital signatures for transactions are the same as in capability 2 with the addition of a requirement that specifies that a Health IT Module must be able to digitally sign a transaction and create the appropriate metadata in conformance with the Provider Profiles Authentication: Registration IG.

4. Gap Certification Eligibility Table for 2015 Edition Health IT Certification Criteria

We define gap certification at 45 CFR 170.502 as the certification of a previously certified Complete EHR or EHR Module(s) to: (1) all applicable new and/or revised certification criteria adopted by the Secretary at subpart C of part 170 based on the test results of a NVLAP-accredited testing laboratory; and (2) all other applicable certification criteria adopted by the Secretary at subpart C of part 170 based on the test results used to previously certify the Complete EHR or EHR Module(s) (for further explanation, see 76 FR 1307–1308). Our gap certification policy

[210] A cryptographic module is defined in FIPS 140–2 as ''a set of hardware, software, firmware, or some combination thereof that implements cryptographic functions or processes, including cryptographic algorithms and, optionally, key generation, and is contained within a defined cryptographic boundary.''

[211] *http://wiki.siframework.org/file/view/esMD%20AoR%20Level%201%20Implementation%20Guide%20v5%20FINAL.docx/539084894/esMD%20AoR%20Level%201%20Implementation%20Guide%20v5%20FINAL.docx.*

[212] *http://wiki.siframework.org/file/view/esMD%20Use%20Case%201%20Implementation%20Guide%20V24%20FINAL.docx/539084920/esMD%20Use%20Case%201%20Implementation%20Guide%20V24%20FINAL.docx.*

focuses on the differences between certification criteria that are adopted through rulemaking at different points in time. This allows health IT to be certified to only the differences between certification criteria editions rather than requiring health IT to be fully retested and recertified to certification criteria (or capabilities) that remain unchanged from one edition to the next and for which previously acquired test results are sufficient. Under our gap certification policy, ''unchanged'' criteria are eligible for gap certification, and each ONC–ACB has discretion over whether it will provide the option of gap certification.

For the purposes of gap certification, Table 4 below provides a crosswalk of proposed ''unchanged'' 2015 Edition certification criteria to the corresponding 2014 Edition certification criteria. We note that with respect to the 2015 Edition certification criteria proposed for adoption at § 170.315(g)(1) through (g)(3) that gap certification eligibility for these criteria is fact-specific and will depend on any modifications made to the specific certification criteria to which these ''paragraph (g)'' certification criteria apply.

TABLE 4—GAP CERTIFICATION ELIGIBILITY FOR 2015 EDITION EHR CERTIFICATION CRITERIA

2015 edition		2014 edition	
Regulation section § 170.315	Title of regulation paragraph	Regulation section § 170.314	Title of regulation paragraph
(a)(1)	Computerized provider order entry—medications.	(a)(1)	Computerized provider order entry.
		(a)(18)	Computerized provider order entry—medications.
(a)(3)	Computerized provider order entry—diagnostic imaging.	(a)(1)	Computerized provider order entry.
		(a)(20)	Computerized provider order entry—diagnostic imaging.
(a)(8)	Medication list	(a)(6)	Medication list.
(a)(9)	Medication allergy list	(a)(7)	Medication allergy list.
(a)(13)	Image results	(a)(12)	Image results.
(a)(16)	Patient list creation	(a)(14)	Patient list creation.
(a)(18)	Electronic medication administration record	(a)(16)	Electronic medication administration record.
(d)(1)	Authentication, access control, and authorization.	(d)(1)	Authentication, access control, and authorization.
(d)(2)	Auditable events and tamper-resistance	(d)(2)	Auditable events and tamper-resistance.
(d)(3)	Audit report(s)	(d)(3)	Audit report(s).
(d)(4)	Amendments	(d)(4)	Amendments.
(d)(5)	Automatic access time-out	(d)(5)	Automatic log-off.
(d)(6)	Emergency access	(d)(6)	Emergency access.
(d)(7)	End-user device encryption	(d)(7)	End-user device encryption.
(d)(8)	Integrity	(d)(8)	Integrity.
(d)(9)	Accounting of disclosures	(d)(9)	Accounting of disclosures.
(e)(2)	Secure messaging	(e)(3)	Secure messaging.
(h)(1)	Direct Project	(b)(1)(i)(A) and (b)(2)(ii)(A).	Transitions of care—receive, display, and incorporate transition of care/referral summaries.
			Transitions of care—create and transmit transition of care/referral summaries.
		(h)(1)	Transmit—Applicability Statement for Secure Health Transport.
(h)(2)	Direct Project, Edge Protocol, and XDR/XDM	(b)(1)(i)(B), (b)(2)(ii)(B), and (b)(8)[213].	Transitions of care—receive, display, and incorporate transition of care/referral summaries.
			Transitions of care—create and transmit transition of care/referral summaries.
			Transitions of care—send and receive via edge protocol.
		(h)(2) and (b)(8)	Transmit—Applicability Statement for Secure Health Transport and XDR/XDM for Direct Messaging.
			Transitions of care—send and receive via edge protocol.
(h)(3)	SOAP Transport and Security Specification and XDR/XDM for Direct Messaging.	(b)(1)(i)(C) and (b)(2)(ii)(C).	Transitions of care—receive, display, and incorporate transition of care/referral summaries.
			Transitions of care—create and transmit transition of care/referral summaries.
		(h)(3)	Transmit—SOAP Transport and Security Specification and XDR/XDM for Direct Messaging.

5. Pharmacogenomics Data—Request for Comment

Pharmacogenomics data identifies genetic variants in individuals that alter their metabolism or other interactions with medications and can lead to serious adverse events. This information is being included in an increasing number of FDA-approved drug labels. Health IT systems that can capture pharmacogenomics information could be used to increase patient safety and enhance patient outcomes.

To our knowledge, in general, health IT has not yet captured genomic and genetic patient information—the presence of clinically significant genomic variants—in a structured manner such as exists for other categorical clinical findings or laboratory-derived data.[214] This information may currently be captured in free text and static PDFs except in a few individual health centers where custom health IT solutions have been developed. However, work on standards and other precursors required for wider adoption is underway, including through the Institute of Medicine, HL7, and LOINC®.[215] Many of these efforts are using pharmacogenomic variations as prototypes because the clinical utility of a subset of such variants has a greater evidence-base, has wide clinical applicability, and is already in clinical use. Pharmacogenomic implementation aims to limit preventable adverse effects and maximize efficacy by using information about genomic variants to enable optimal drug choices and patient-specific dosing.

For the use case of CDS informed by pharmacogenetic information, considerable ambiguity exists with respect to the incorporation of CDS systems that facilitate providers taking advantage of pharmacogenomic information.[216] Thus, there is an opportunity for further specification of standards and implementation of pharmacogenomic data for CDS within health IT systems. We also believe there may be opportunities for capturing genomic patient data in laboratory results, for drug-genome interactions, and for genomic metabolizer status (defined risks to certain medications) in a structured way within health IT.

Note that we have previously adopted a 2014 Edition ''family health history'' certification criterion that referenced the HL7 standard for representing genomic information and are proposing a 2015 Edition ''family health history—pedigree'' certification criterion that references that same standard as well as a related IG. In addition to their relevance for the tested patient, genomic test results are unique in that they have the potential to inform the health care of blood relatives of the tested individual, similar to a shared family history. We note that any application of genomic information across family members must be done in accordance with the HIPAA Privacy Rule and other privacy and patient rights laws regarding genetic information at the federal and state levels.

We acknowledge that individually identifiable genetic information may be subject to federal and state privacy laws and regulations that are more privacy restrictive than the HIPAA Privacy Rule. As such, these privacy issues will impact any certification criteria or policy we might propose to adopt in future rulemaking. We therefore welcome input on factors to consider for health IT that allows the user to use or disclose genetic information in a manner compliant with federal and state privacy laws. Note that we are proposing two new 2015 Edition certification criteria for ''data segmentation for privacy—send'' and ''data segmentation for privacy—receive'' that would focus on the capability to separately track (''segment'') individually identifiable health information that is protected by rules that are more restrictive than the HIPAA Privacy Rule (please refer to Section III.A.3 for more information). We believe that the capabilities offered by the proposed ''data segmentation for privacy'' criteria could be leveraged for the segmentation of individually identifiable genetic information that are protected by federal and state privacy laws and regulations.

We also acknowledge that the inclusion of genomic information in health IT-related mechanisms will need to be carefully implemented to balance the benefit to patients while avoiding discrimination against persons with or at risk for the development of future health issues, and their family members.

In collaboration with the National Institutes of Health, we solicit comment on whether:

- The 2015 Edition ''medication allergy list'' certification criterion should include the capability to integrate genotype-based drug metabolizer rate information.
- The 2015 Edition ''drug-drug, drug-allergy interactions checks for CPOE'' certification criterion or as a separate certification criterion should include pharmacogenomic CDS for ''drug-genome interactions.''
- We should offer 2015 Edition certification for CDS that incorporate a patient's pharmacogenomic genotype data into the CPOE prescribing process with the goal of avoiding adverse prescribing outcomes for known drug-genotype interactions.
- There are certification approaches that could enhance the end-user's (provider's) adoption and continued use of health IT implementations that guide prescribing through CDS using pharmacogenomic data.
- There are existing or developing standards applicable to the capture, storage, display, and exchange of potentially clinically relevant genomic data, including the pharmacogenomic subset.
- We should offer certification for health IT functionality that could facilitate HIPAA-compliant sharing of discrete elements of a patient's genomic information from their record to the family history section of a relative's record.
- The proposed ''data segmentation for privacy'' criteria would provide needed health IT functions with respect to the storage, use, transmission, and disclosure of genetic, genomic, and pharmacogenomics information that is subject to protections under HIPAA and

[213] Technology must have been certified to both edge protocol methods specified by the standard in § 170.202(d) to be gap certification eligible.

[214] *http://www.genomebc.ca/education/articles/genomics-vs-genetics/;* and *http://www.who.int/genomics/geneticsVSgenomics/en/.*

[215] Clinical Pharmacogenetics Implementation Consortium, *http://www.pharmgkb.org/page/cpic/*; electronic medical records and genomics Network (eMERGE), *http://emerge.mc.vanderbilt.edu/emerge-network* and *http://emerge.mc.vanderbilt.edu/emerge-publications-0*; Clinical Sequencing Exploratory Research (CSER) *https://cser-consortium.org;* Implementing Genomics in Practice (IGNITE), *http://www.ignite-genomics.org/IGNITE_ABOUT.html;* Institute of Medicine (IOM) Action Collaborative, *http://www.iom.edu/Activities/Research/GenomicBasedResearch.aspx;* NHGRI GM7, Genomic Medicine Centers Meeting VII action items relating to pharmacogenomics implementation, *http://www.genome.gov/Multimedia/Slides/GM7/09_Williams-Middleton.pdf;* Clinical Genome Resource, *http://www.clinicalgenome.org/about/;* Clinical Variation Aggregation Database, *https://www.ncbi.nlm.nih.gov/clinvar/; and* HL7 Clinical Genomics Working Group, *http://www.hl7.org/Special/committees/clingenomics/index.cfm.*

[216] Overby CL, Kohane I, Kannry J, et al, *Opportunities for Genomic Clinical Decision Support Interventions,* Genet Med. 2013 October 2015(10):817–23; Rasmussen-Torvik LJ, Stallings SC, Gordon AS, et al, *Design and Anticipated Outcomes of the eMERGE–PGx Project: A Multi-Center Pilot for Pre-Emptive Pharmacogenomics in Electronic Health Record Systems,* Clin Pharmacol Ther. 2014 Jun 24. doi: 10.1038/clpt.2014.137, [Epub ahead of print]; Karnes JH, Van Driest S, Bowton EA, et al, *Using systems approaches to address challenges for clinical implementation of pharmacogenomics,* Wiley Interdiscip Rev Syst Biol Med. 2014 Mar-Apr;6(2):125–35, doi:10.1002/wsbm.1255. Epub 2013 Dec 6; and Peterson JF, Bowton E, Field JR, et al, *Electronic health record design and implementation for pharmacogenomics: a local perspective,* Genet Med. 2013 Oct;15(10):833–41. doi: 10.1038/gim.2013.109. Epub 2013 Sep 5.

additional state and federal privacy and protection laws such as the Genetic Information Nondiscrimination Act (GINA).[217]

• The proposed ''data segmentation for privacy'' criteria adequately balance complex genetic privacy issues, such as those related to behavioral health, with the clinical value of context-appropriate availability of a patient's actionable genetic and genomic information.

• Health IT should be required to apply different rules for the use and exchange of genetic, genome, and pharmacogenomics data based on different groupings of diseases or conditions based on the sensitivity of the information, such as those related to behavioral health.

• There are other factors we should consider for health IT that allows the user to use or disclose genetic information in a manner compliant with federal and state privacy laws.

B. Definitions

1. Base EHR Definitions

We propose to adopt a Base EHR definition specific to the 2015 Edition (*i.e.,* a 2015 Edition Base EHR definition) at § 170.102 and rename the current Base EHR definition at § 170.102 as the 2014 Edition Base EHR definition. To effectively rename the current Base EHR definition as the ''2014 Edition Base EHR'' definition, the Base EHR definition must be removed from the CFR and a ''2014 Edition Base EHR'' definition must be added. This is a procedural requirement and we affirm that the definition itself is not changing. However, for the proposed 2015 Edition Base EHR definition, it would differ from the 2014 Edition Base EHR definition in the following ways:

• It does not include privacy and security capabilities and certification criteria. We believe privacy and security capabilities would be more appropriately addressed through our new proposed approach for the privacy and security certification of Health IT Modules to the 2015 Edition, as discussed under ''Privacy and Security'' in section IV.C.1 of this preamble. Our new privacy and security approach would eliminate EPs', eligible hospitals', and CAHs' responsibilities to ensure that they have technology certified to all the necessary privacy and security criteria. Rather, as part of certification, health IT developers would need to meet applicable privacy and security certification criteria.

• It only includes capabilities to record and export CQM data (§ 170.315(c)(1)). To note, the capabilities to import, calculate and report CQM data are not included in the proposed 2015 Edition Base EHR definition or any other CQM-related requirements. Please refer to the ''Clinical Quality Measures'' section (III.A.3) earlier in this preamble for a more detailed discussion of the CQM certification criteria. Please also see the EHR Incentive Programs Stage 3 proposed rule published elsewhere in this issue of the **Federal Register** for proposals related to CQMs, including the CEHRT definition proposal.

• It includes the 2015 Edition ''smoking status'' certification criterion as patient demographic and clinical health information data consistent with statutory requirements.[218] Smoking and the use of tobacco in general is the number one cause of preventable death and disease in the United States. By including this capability and criterion in the definition, it ensures that providers participating in the EHR Incentive Programs have the basic capability to capture the smoking status of patients, which permits more providers to take part in addressing (through intervention and cessation efforts) this cause of preventable disease and death.

• It includes the 2015 Edition ''implantable device list'' certification as patient demographic and clinical health information data consistent with statutory requirements.[219] The ability to record and access a patient's unique device identifiers can improve patient safety. Please see the discussion under the ''implantable device list'' certification criterion for further benefits derived from providers having access unique device identifier(s) for a patient's implantable device(s).

• It includes the 2015 Edition ''application access to Common Clinical Data Set'' certification criterion as a capability to both capture and query information relevant to health care quality and exchange electronic health information with, and integrate such information from other sources.[220] Due to the proposed inclusion of the 2015 Base EHR definition in the proposed CEHRT definition (see ''CEHRT definition'' section below and in the EHR Incentive Programs Stage 3 proposed rule published elsewhere in this issue of the **Federal Register**), like all capabilities and criteria included in the 2015 Edition Base EHR definition, this would ensure that all EPs, eligible hospitals, and CAHs would need to adopt a Health IT Module certified to this criterion in order to have the necessary health IT to meet the CEHRT definition. As such, the inclusion of the 2015 Edition ''application access to Common Clinical Data Set'' certification criterion in the 2015 Edition Base EHR definition could further facilitate health information exchange by being specifically used to meet meaningful use objectives and measures as well as through it simply being readily available for use by these providers and their patients.

• It includes the proposed 2015 Edition Health IT certification criteria that correspond to the remaining 2014 Edition certification criteria referenced in the ''2014 Edition'' Base EHR definition (*i.e.,* CPOE, demographics, problem list, medication list, medication allergy list, CDS, transitions of care, data portability, and relevant transport certification criteria). On the inclusion of transport certification criteria, we propose to include the ''Direct Project'' criterion (§ 170.315(h)(1)) as well as the ''Direct Project, Edge Protocol and XDR/XDM'' criterion (§ 170.315(h)(2)) as equivalent alternative means for meeting the 2015 Edition Base EHR definition for the reasons discussed earlier in this preamble under the ''Transport Methods and Other Protocols'' section.

[217] *http://ghr.nlm.nih.gov/spotlight=thegeneticinformationnondiscriminationactgina.*

[218] A Base EHR is the regulatory term we have given to what the HITECH Act defines as a ''qualified EHR.'' Our Base EHR definition(s) include all capabilities found in the ''qualified EHR.'' Please see the 2014 Edition final rule (77 FR 54262) for further explanation.

[219] A capability included in the Base EHR definition, which originates from the ''qualified EHR'' definition found in the HITECH Act.

[220] These are capabilities included in the Base EHR definition, which originate from the ''qualified EHR'' definition found in the HITECH Act.

TABLE 5—CERTIFICATION CRITERIA REQUIRED TO SATISFY THE 2015 EDITION BASE EHR DEFINITION

Base EHR capabilities	Certification criteria
Includes patient demographic and clinical health information, such as medical history and problem lists.	Demographics § 170.315(a)(5) Problem List § 170.315(a)(7) Medication List § 170.315(a)(8) Medication Allergy List § 170.315(a)(9) Smoking Status § 170.315(a)(12) Implantable Device List § 170.315(a)(20)
Capacity to provide clinical decision support	Clinical Decision Support § 170.315(a)(10)
Capacity to support physician order entry	Computerized Provider Order Entry § 170.315(a)(1), (2) or (3)
Capacity to capture and query information relevant to health care quality.	Clinical Quality Measures § 170.315(c)(1)
Capacity to exchange electronic health information with, and integrate such information from other sources.	Transitions of Care § 170.315(b)(1) Data Portability § 170.315(b)(6) Application Access to Common Clinical Data Set § 170.315(g)(7) Direct Project § 170.315(h)(1) or Direct Project, Edge Protocol, and XDR/XDM § 170.315(h)(2)

Marketing

We note that we would continue the same marketing policy that we adopted for the 2014 Edition as it relates to the 2015 Edition Base EHR definition (*i.e.,* health IT developers would have the ability to market their technology as meeting the 2015 Edition Base EHR definition when their Health IT Module(s) is/are certified to all the 2015 Edition health IT certification criteria included in the 2015 Edition Base EHR definition).

2. Certified EHR Technology Definition

We propose to remove the Certified EHR Technology (CEHRT) definition from § 170.102, effective with a subsequent final rule for the following reasons. The CEHRT definition has always been defined in a manner that supports the EHR Incentive Programs. As such, the CEHRT definition would more appropriately reside solely within the EHR Incentive Programs regulations. This would also be consistent with our approach in this proposed rule to make the ONC Health IT Certification Program more open and accessible to other types of health IT beyond EHR technology and for health IT that supports care and practice settings beyond those included in the EHR Incentive Programs. Further, this approach should add administrative simplicity in that regulatory provisions, which EHR Incentive Programs participants must meet (*e.g.,* the CEHRT definition), would be defined within the context of rulemakings for those programs.

The EHR Incentive Programs currently include a regulatory definition of CEHRT in 42 CFR 495.4 that simply adopts the CEHRT definition in § 170.102. As proposed in the EHR Incentive Programs Stage 3 proposed rule, published elsewhere in this issue of the **Federal Register**, CMS would adopt a CEHRT definition in 42 CFR 495.4 that would cover all relevant compliance timelines (*i.e.,* specify the CEHRT definition applicable for each year/EHR reporting period) and EHR Incentive Programs requirements. The CEHRT definition proposed by CMS would also continue to point to the relevant Base EHR definitions [221] adopted or proposed by ONC and to other ONC-adopted and proposed certification criteria relevant to the EHR Incentive Programs. We refer readers to EHR Incentive Programs Stage 3 proposed rule for further details regarding the CEHRT definition proposal.

3. Common Clinical Data Set Definition

We propose to revise the ''Common MU Data Set'' definition in § 170.102. We propose to change the name to ''Common Clinical Data Set,'' which aligns with our approach throughout this proposed rule to make the ONC Health IT Certification Program more open and accessible to other types of health IT beyond EHR technology and for health IT that supports care and practice settings beyond those included in the EHR Incentive Programs. To effectively rename the Common MU Data Set as the ''Common Clinical Data Set,'' the Common MU Data Set definition must be removed from the CFR and the ''Common Clinical Data Set'' definition must be added. This is a procedural requirement and all substantive changes to the definition would only affect certification to the 2015 Edition. We also propose to change references to the ''Common MU Data Set'' in the 2014 Edition (§ 170.314) to ''Common Clinical Data Set.''

We propose to revise the definition to account for the new and updated standards and code sets we propose to adopt in this proposed rule that would improve and advance interoperability through the exchange of the Common Clinical Data Set. We also propose to revise the definition to support patient safety through clearly referenced data elements and the inclusion of new patient data. These proposed revisions would *not* change the standards, codes sets, and data requirements specified in the Common Clinical Data Set for 2014 Edition certification. They would only apply to a Health IT Module certified to the 2015 Edition Health IT certification criteria that reference the Common Clinical Data Set.

Vocabulary Standards

We propose to include HL7 Version 3 (''AdministrativeGender'' and a nullFlavor value) for sex, ''Race & Ethnicity—CDC'' code system in PHIN VADS and the OMB standard for race and ethnicity, RFC 5646 for preferred language, the September 2014 Release of the U.S. Edition of SNOMED CT® for problems and procedures, the February 2, 2015 monthly version of RxNorm for medications and medication allergies, LOINC® version 2.50 for laboratory tests, and the LOINC® codes, metadata, and relevant UCUM unit of measures specified for vital signs as discussed under the ''vital signs, BMI and growth charts'' certification criterion in section III.A.3 of this preamble. We note that for race and ethnicity a Health IT Module must be able to express both detailed races and ethnicities according to the ''Race & Ethnicity—CDC'' code system and the aggregate OMB code for each race and ethnicity identified by the patient.

We propose to include immunizations in the ''Common Clinical Data Set'' for 2015 Edition certification. As described

[221] This is required by the HITECH Act under the term ''Qualified EHR'' and references a foundational set of certified capabilities all EPs, eligible hospitals, and CAHs need to adopt.

in more detail in the preamble for the ''transmission to immunization registries'' certification criterion in section III.A.3, the C–CDA Release 2.0 can support NDC codes as a translational data element, but the CVX code is required to accompany it. The NDC code contains more information than the CVX code, such as packaging information, that can assist with tracking for clinical trials and adverse events. We believe that it would not be a heavy burden to map from an NDC code to a CVX code because a mapping from NDC codes to CVX codes is publicly available.[222] Therefore, for the purposes of including immunizations in the ''Common Clinical Data Set'' for 2015 Edition certification, immunizations would be required to be coded according to the CVX code set (HL7 Standard Code Set CVX—Vaccines Administered, updates through February 2, 2015) and the NDC code set (NDC—Vaccine Codes, updates through January 15, 2015) as part of the ''Common Clinical Data Set.''

Unique Device Identifier(s)

We also propose to include the Unique Device Identifier(s) of a patient's Implantable Device(s) for certification to the 2015 Edition. As discussed under the ''implantable device list'' certification criterion, this information leads to improved patient safety when available to providers. By including this information in the Common Clinical Data Set, a Health IT Module certified to criteria referencing the Common Clinical Data Set would be capable of exchanging this information and further facilitating improvements in patient safety.

Assessment and Plan of Treatment, Goals, and Health Concerns

We propose to include the ''assessment and plan of treatment,'' ''goals,'' and ''health concerns'' in the ''Common Clinical Data Set'' for certification to the 2015 Edition. The ''assessment and plan of treatment,'' ''goals,'' and ''health concerns'' are intended to replace the concept of the ''care plan field(s), including goals and instructions'' which is part of the ''Common MU Data Set'' in the 2014 Edition. Based on conversations with stakeholders, we are aware that the ''care plan field(s), including goals and instructions'' may be interpreted in two different ways. It might be interpreted to mean the assessment, plan of care (for treatment), goals, and health concerns documented for a single patient encounter (in ambulatory settings) or for the duration of an inpatient stay (in inpatient settings). However, ''care plan field(s), including goals and instructions'' could also be interpreted to mean a comprehensive shared care plan that represents the synthesis and reconciliation of multiple plans of care (for treatment) produced by each provider to address specific health concerns. Stakeholders have indicated that in implementation, they have interpreted ''care plan field(s), including goals and instructions'' in the ''Common MU Data Set'' as the assessment, plan of care (for treatment), goals, and health concerns *for a single patient encounter or inpatient stay.* These stakeholders have expressed safety concerns that the volume of data in a comprehensive care plan can be so extensive that it may be difficult for a provider to quickly determine the information of value for the patient for the given situation.

In consideration of this feedback, we clarify that we intend ''care plan field(s), including goals and instructions'' to be a single provider's documentation of their assessment, plan of treatment, goals, and health concerns for the patient (this clarification applies for 2014 Edition certification). We also make this clarification to better align with the terms used in the C–CDA Release 2.0, which includes the ''Assessment and Plan Section (V2),'' ''Assessment Section (V2),'' ''Plan of Treatment Section (V2),'' ''Goals Section,'' and ''Health Concerns Section.'' In previous iterations of the C–CDA, the ''Plan of Treatment Section'' was called the ''Plan of Care Section,'' which resulted in the same level of confusion on whether the information was intended to represent a single encounter or the synthesis of multiple encounters. For that reason, the ''Plan of Care Section'' is now called the ''Plan of Treatment Section'' to indicate that it is intended to represent a single encounter and not to be confused with the ''Care Plan document template.''

For certification to the 2015 Edition, we propose to include in the Common Clinical Data Set ''assessment and plan of treatment,'' ''goals,'' and ''health concerns'' data in accordance with the C–CDA Release 2.0 ''Assessment and Plan Section (V2)'' or both the ''Assessment Section (V2)'' and ''Plan of Treatment Section (V2);'' the ''Goals Section;'' and the ''Health Concerns Section.'' In practice, health care providers may document the assessment and plan of treatment together or separately, and the C–CDA Release 2.0 provides for both modes of practice. We understand that the C–CDA Release 2.0 permits both free-text and structured documentation of the assessment, plan of treatment, goals, and health concerns information in the sections named above. While we do not propose to require that this information is documented in a structured way, we encourage health IT developers to allow for structured documentation or tagging that would allow a provider to choose relevant pieces of assessment, plan of treatment, goals, and health concerns data that could be synthesized into a comprehensive care plan. We note that all proposed 2015 Edition certification criteria that reference the ''Common Clinical Data Set'' (*e.g.,* the ToC criterion) would therefore also require a Health IT Module to be able to capture ''assessment and plan of treatment,'' ''goals,'' and ''health concerns'' data.

We continue to believe in the value of a comprehensive care plan and discuss our proposal for a 2015 Edition certification criterion for this functionality in Section III.A.3 of the preamble (see the ''care plan'' certification criterion). As stated above, a comprehensive care plan may contain a large volume of data that is burdensome to transmit for the purposes of sharing information relevant for a single encounter or inpatient stay, and thus we do not propose to include it in the ''Common Clinical Data Set'' definition.

Alignment With Clinical Practice

We recognize that the data included in the Common Clinical Data Set may change over time. Therefore, we request comment on ways in which we can engage the public to keep the Common Clinical Data Set relevant to clinical practice.

4. Cross Referenced FDA Definitions

As discussed in our proposal for the 2015 Edition ''implantable device list'' certification criterion, we propose to adopt in § 170.102 new definitions for ''Implantable Device,'' ''Unique Device Identifier,'' ''Device Identifier,'' and ''Production Identifier.'' We propose to adopt the same definitions already provided to these phrases at 21 CFR 801.3. Again, we believe adopting these definitions in our rule will prevent any interpretation ambiguity and ensure that each phrase's specific meaning reflects the same meaning given to them in the Unique Device Identification System final rule at 21 CFR 801.3. Capitalization was purposefully applied to each word in these defined phrases in order to signal to readers that they have specific meanings.

[222] *http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=ndc.* See also: *http://www2a.cdc.gov/vaccines/iis/iisstandards/ndc_tableaccess.asp.*

IV. Provisions of the Proposed Rule Affecting the ONC Health IT Certification Program

A. Subpart E—ONC Health IT Certification Program

We propose to replace the term ''HIT'' with the term ''health IT'' wherever it may occur in subpart E. While ''HIT'' is a term used in the HITECH Act, we believe the term ''health IT'' offers more clarity than ''HIT'' for stakeholders. Similarly, we propose to replace the ''ONC HIT Certification Program'' with ''ONC Health IT Certification Program'' wherever it may occur in subpart E. In referring to the certification program, the term ''health'' is capitalized. We also propose to remove § 170.553 ''Certification of health information technology other than Complete EHRs and EHR Modules'' as we believe this section is no longer relevant based on our proposals for the ONC Health IT Certification Program discussed in more detail below.

B. Modifications to the ONC Health IT Certification Program

In the Voluntary Edition proposed rule (79 FR 10929–30) we recited our authority and the history of the ONC Health IT Certification Program, including multiple requests for comment and significant feedback on making the program more accessible to health IT beyond EHR technology and health care settings and practices not directly tied to the EHR Incentive Programs. With consideration of stakeholder feedback and our policy goals, we attempted to make the ONC Health IT Certification Program more open and accessible through a proposal in the Voluntary Edition proposed rule (79 FR 10918–20) to create MU and non-MU EHR Modules. We subsequently determined that our proposal was not the best approach (79 FR 54472–73). Since that rulemaking, the HITPC has issued recommendations supporting certification for care/practice settings beyond the ambulatory and inpatient settings.[223] We have also reconsidered how best to structure the program and make it open and accessible to more types of health IT, health IT that supports a variety of care and practice settings, and programs that may reference the ONC Health IT Certification Program, including Medicaid and Medicare payment programs and various grant programs.

1. Health IT Modules

We propose to rename EHR Modules as Health IT Modules. To effectively rename EHR Modules as Health IT Modules, the EHR Module definition must be removed from the CFR at § 170.102 and a ''Health IT Module'' definition must be added. This proposed change would be effective on the effective date of a subsequent final rule, which would make this change applicable for certification to the 2014 Edition and 2015 Edition (if adopted). An EHR Module is defined in § 170.102 as any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary. The definition essentially covers any type of technology that could be certified to one or more certification criterion under the ONC Health IT Certification Program. As such, our proposed change will have no substantive impact on the technologies that might be, or have been, certified under the ONC Health IT Certification Program. We believe this proposal best addresses the full range of health IT that has and might be certified to adopted certification criteria now and in the future. This approach also gives more appropriate attribution to certifications issued to technologies that would not generally be considered ''EHR'' functionality, such as functionality provided by a HISP, HIE, or LIS. The switch to ''Health IT Module'' could also have long-term practicality as the ONC Health IT Certification Program evolves.

For technologies already certified to the 2014 Edition as EHR Modules, this proposal would not affect the certification of those technologies or the ability to use those technologies to meet the CEHRT definition. Further, we see no reason why these technologies could not be called Health IT Modules if the developer wished to do so. We suggest, however, that health IT developers check with the ONC–ACB that issued the certification to ensure this would be permissible based on the issued certification.

We also emphasize that a Health IT Module is simply the name for a technology that gets issued a certification under the ONC Health IT Certification Program. One Health IT Module certification or multiple Health IT Modules certifications can be of sufficient scope to meet the Base EHR definition and even the CEHRT definition.

2. ''Removal'' of Meaningful Use Measurement Certification Requirements

We propose to *not* require ONC–ACBs to certify Health IT Modules to the 2015 Edition ''meaningful use measurement'' certification criteria (§ 170.315(g)(1) ''automated numerator recording'' and § 170.315(g)(2) ''automated measure calculation''). This is a change from prior certification policy, such as with the certification of technology to the 2014 Edition and the requirements of § 170.550(f)(1). We believe this will make the ONC Health IT Certification more accessible to the certification of health IT for other purposes beyond the EHR Incentive Programs. Further, we have received feedback from stakeholders that these requirements can pose a significant burden on health IT development and come at the cost of improving clinical functionality and usability (79 FR 54469). We have also heard from stakeholders that these criteria can impact innovation. Whether this feedback is entirely accurate is not the primary reason for our changed approach. Rather, we believe that not all health IT certified under the ONC Health IT Certification Program needs to have these capabilities and that it is more appropriate to align our approach to these criteria with our primary policy of administering a certification program that includes certification criteria that broadly support the health care system, while making available for health IT developers the flexibility to present their health IT for certification to the criteria that support their specific customers' and providers' needs.

We emphasize that this proposed approach *does not preclude* health IT developers from seeking certification to § 170.315(g)(1) or (2) in support of their customers' and provider's needs related to the EHR Incentive Programs. Moreover, the EHR Incentive Programs Stage 3 proposed rule, published elsewhere in this issue of the **Federal Register**, includes a proposed CEHRT definition that would require EPs, eligible hospitals, and CAHs to have health IT certified to these criteria in order to meet the CEHRT. Accordingly, health IT developers supporting providers participating the EHR Incentive Programs should strongly consider seeking certification to these certification criteria, as applicable.

3. Types of Care and Practice Settings

As noted above, the HITPC issued recommendations generally supporting certification for a variety of care and practice settings under the ONC Health IT Certification Program, particularly

[223] *http://www.healthit.gov/facas/sites/faca/files/TransmittalLetter_LTPAC_BH_Certification.pdf* and *http://www.healthit.gov/facas/sites/faca/files/HITPC_LTPAC_BH_Certification_Recommendations_FINAL.pdf.*

focusing on long-term post-acute care (LTPAC) and behavioral health settings. Consistent with those recommendations, we have made proposals to make the ONC Health IT Certification Program more agnostic to care and practice settings (*e.g.,* the proposals to revise § 170.300 and ''remove'' ''meaningful use measurement'' certification requirements) and we have proposed new ''data segmentation'' certification criteria (§§ 170.315(b)(7) and (8)) that include capabilities that can support care and practice settings that service patients with sensitive health information, including behavioral health.

In the Voluntary Edition final rule (79 FR 54473), we pointed stakeholders to the guidance we issued in 2013 for health IT developers serving providers ineligible for the EHR Incentives Programs. The guidance, ''Certification Guidance for EHR Technology Developers Serving Health Care Providers Ineligible for Medicare and Medicaid EHR Incentive Payments,'' [224] was developed in close coordination with HHS agencies, including the Substance Abuse and Mental Health Services Administration (SAMHSA). The guidance is designed for certification to the 2014 Edition and focuses on two key area, interoperability-focused certification criteria (highlighting the ''transitions of care'' and ''clinical information reconciliation'' criteria as criteria that support interoperable summary care record exchange—a fundamental capability necessary to enable care coordination across different settings) and privacy and security certification criteria. The HITPC similarly concluded that LTPAC and behavioral health providers should focus on adopting health IT certified to these capabilities (certification criteria).[225]

The 2015 Edition includes many certification criteria with the same capabilities as those certification criteria identified in the 2014 guidance, but with new and/or enhanced functionality. As one pertinent example, the 2015 Edition ''transitions of care'' certification criterion (§ 170.315(b)(1)) includes capabilities for formatting a care/referral summary according to the Common Clinical Data Set and the C–CDA Release 2.0. The C–CDA Release 2.0 includes new document templates for: Care Plan; Referral Note; Transfer Summary, and new sections for: Goals; Health Concerns; Health Status Evaluation/Outcomes; Mental Status; Nutrition; Physical Findings of Skin and new entries (*e.g.* Wound Observation) that may be particularly beneficial to providers that serves medically-complex patients with chronic care conditions. As to privacy and security, we highlight that our new proposed approach in this rule focuses on ensuring that all health IT presented for certification is certified to the appropriate privacy and security certification criteria. Overall, we have proposed a diverse edition of health IT certification criteria with capabilities included that could support a wide range of providers practicing in various settings.

We anticipate that, similar to the 2014 Edition guidance, we would issue general interoperability guidance for the 2015 Edition when it becomes final. However, we have no plans to *independently* develop and issue certification ''paths'' or ''tracks'' by care or practice setting (*e.g.,* a ''LTPAC certification'') as it would be difficult to independently devise such ''paths'' or ''tracks'' in a manner that was sure to align with other relevant programs and specific stakeholder needs. Rather, we believe we are best suited for supporting the development of standards for specific settings/use cases and providing technical assistance to both health IT developers and providers about the certification criteria, the standards and capabilities they include, and the processes of the ONC Health IT Certification Program. In this regard, we would welcome working with HHS or other agencies, or provider associations, in identifying the appropriate functionality and certification criteria to support their stakeholders, including jointly developing specialized certification ''paths'' or ''tracks.'' To note, we believe this approach is also consistent with stakeholder feedback we received through rulemaking (79 FR 54473–74) and the HITPC recommendations for us to work with HHS and other agencies.

We seek comment on potential future certification criteria that could include capabilities that would uniquely support LTPAC, behavioral health, or pediatrics care\practice settings, as well as other settings. We are specifically interested in public comment on whether certification criteria focused on patient assessments (*e.g.,* Minimum Data Set (Nursing Homes), OASIS (Home Health), IRF–PAI (Inpatient Rehabilitation Facility), or Long Term Care Hospital (CARE data set) would support key functionality needed in these settings and if there standards mature enough for structured patient assessments. Similarly, we seek comment on whether certification criteria focused on patient assessments for behavioral health settings would be of value to health IT developers and health care providers.

4. Referencing the ONC Health IT Certification Program

Our proposals throughout this proposed rule, including the proposed adoption of various criteria that support functionality for different care and practice settings and the proposals to make the ONC Health IT Certification Program open and accessible to more types of health IT and health IT that supports a variety of care and practice settings, would permit further referencing and use of certified health IT.

Currently, in addition to the EHR Incentive Programs, the adopted certification criteria editions already support and are referenced by other HHS programs (*e.g.,* the CMS and HHS Office of Inspector General (OIG) final rules to modify the Physician Self-Referral Law exception and Anti-kickback Statute safe harbor for certain EHR donations (78 FR 78751) and (78 FR 79202), respectively).[226] Certified health IT has also been referenced in CMS payment rules such as the CY 2015 Physician Fee Schedule final rule (79 FR 67721–28) for chronic care management services and in a proposed rule (79 FR 61186) encouraging the use of certified health IT by home health agencies. The Department of Defense has also referenced certified health IT in a request for proposal for its Healthcare Management System Modernization Program.[227] In the private sector, The Joint Commission requires the use of certified health IT to participate as an Outcomes Research Yields Excellence (ORYX) vendor and submit electronic clinical quality measures on behalf of hospitals.[228]

The proposed 2015 Edition and proposed open and flexible certification processes in this proposed rule would continue to facilitate the efforts

[224] *http://www.healthit.gov/sites/default/files/generalcertexchangeguidance_final_9-9-13.pdf.*

[225] *http://www.healthit.gov/facas/sites/faca/files/TransmittalLetter_LTPAC_BH_Certification.pdf* and *http://www.healthit.gov/facas/sites/faca/files/HITPC_LTPAC_BH_Certification_Recommendations_FINAL.pdf.*

[226] CMS final rule, ''Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships: Exception for Certain Electronic Health Records Arrangements'' (78 FR 78751) (December 27, 2013). OIG final rule, ''Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute'' (78 FR 79202) (December 27, 2013).

[227] *https://www.fbo.gov/index?s=opportunity&mode=form&id=573cfbaa71e7843341a7c145888c48e0&tab=core&_cview=1.*

[228] *http://www.jointcommission.org/assets/1/18/2015_eCQM_Vendor_List.pdf.* (page 3).

described above as well as other ongoing and future efforts to reference and use certified health IT.

C. Health IT Module Certification Requirements

1. Privacy and Security

We propose a new approach for privacy and security (P&S) certification to the 2015 Edition. In our past rulemakings, we have discussed and instituted two different policy approaches and sought comment on others for ensuring that health IT and providers have privacy and security capabilities while also trying to minimize the level of regulatory burden imposed on health IT developers. In the 2011 Edition, we included an upfront requirement that required Health IT Modules to meet all P&S certification criteria as a condition of certification unless the health IT developer could demonstrate that certain P&S capabilities were either technically infeasible or inapplicable. In the 2014 Edition, we eliminated the upfront requirement for each Health IT Module to be certified against the P&S criteria in favor of what we thought would better balance the burden potentially posed by our rulemaking. Thus, the P&S criteria were made part of the ''2014 Edition Base EHR definition'' that all EPs, EHs, and CAHs must meet in order to satisfy the CEHRT definition (meaning each provider needed, post-certification to ultimately have technology certified to the P&S criteria).

On March 23, 2013, the HITSC recommended that we should change our certification policy for P&S. They recommended that each Health IT Module presented for certification should be certified through one or more of the following three paths:

- Demonstrate, through system documentation and certification testing, that the Health IT Module includes functionality that meets at least the ''minimal set'' [229] of privacy and security certification criterion.
- Demonstrate, through system documentation sufficiently detailed to enable integration, that the Health IT Module has implemented service interfaces that enable it to access external services necessary to conform to the ''minimal set'' of privacy and security certification criterion.
- Demonstrate through documentation that the privacy and security certification criterion (and the minimal set that the HITSC defined) is inapplicable or would be technically infeasible for the Health IT Module to meet. In support of this path, the HITSC recommended that ONC develop guidance on the documentation required to justify inapplicability or infeasibility.

In response to the HITSC recommendations and stakeholder feedback we sought comment in the Voluntary Edition proposed rule (79 FR 10925–26) on the following four options we believed could be applied to Health IT Module certification for privacy and security: (1) Re-adopt the 2011 Edition approach; (2) maintain the 2014 Edition approach; (3) adopt the 2013 HITSC recommendation; or (4) adopt a limited applicability approach—under which ONC would establish a limited set of P&S functionality that every Health IT Module would be required to address in order to be certified.

In response to our request for comments, we received comments generally in support of the 2014 approach (including P&S in the Base EHR definition). While some commenters supported requiring a subset of P&S criteria (option 4), many disagreed on the scope and did not see the value vis-a-vis HIPAA compliance. The HITSC preferred a different option. They recommended that ONC revise each privacy and security criterion to specify the conditions under which it is applicable (similar to how the end-user device encryption criterion currently is written), and allow each criterion to be met using one of the three paths the HITSC recommended in 2013.[230]

During their discussions regarding the Voluntary Edition proposed rule, the HITSC's Privacy and Security Workgroup (PSWG) completed an assessment of which P&S functionality should be required for each proposed certification criterion. The PSWG recognized that the privacy and security criteria are not equally applicable or useful to every criterion in each of the other regulatory functional areas (*i.e.,* clinical, care coordination, clinical quality, patient engagement, public health, utilization, and transmission) because each P&S criterion is designed to address specific risk conditions that may or may not be present within a specific regulatory functional area.

The PSWG model allows for the appropriate safeguards to be in place for each criterion, without overburdening health IT developers by requiring them to include all P&S functionality for each criterion. We believe this serves as a good model, in combination with the 2013 HITSC recommendations, to propose a new, simpler, straight-forward approach to the P&S certification requirements for Health IT Modules that merges many of the recommendations and feedback we have received to date. Under the proposed approach, a health IT developer would know exactly what it needed to do in order to get its Health IT Module certified and a purchaser of a Health IT Module would know exactly what privacy and security functionality against which the Health IT Module had to be tested in order to be certified.

We propose to require that an ONC–ACB must ensure that a Health IT Module presented for certification to any of the certification criteria that fall into each regulatory text ''first level paragraph'' category (*e.g.,* § 170.315(a)) of § 170.315 identified below is certified to either approach 1 (technically demonstrate) or approach 2 (system documentation) as follows:

[229] The minimal set includes the following certification criteria: ''authentication, access control, and authorization,'' ''auditable events and tamper resistance,'' ''audit report(s),'' ''amendments,'' ''automatic log-off,'' ''emergency access,'' ''end-user device encryption,'' and ''integrity.'' The full recommendation can be found at: *http://www.healthit.gov/sites/default/files/pswgtransmittalmemo_032613.pdf.*

[230] *http://www.healthit.gov/sites/default/files/pswgtransmittalmemo_032613.pdf.*

If the Health IT Module includes capabilities for certification listed under:	It will need to be certified to approach 1 or approach 2 for each of the P&S certification criteria listed in the ''approach 1'' column	
	Approach 1	Approach 2
§ 170.315(a)	§ 170.315(d)(1) (authentication, access control, and authorization), (d)(2) (auditable events and tamper resistance), (d)(3) (audit reports), (d)(4) (amendments), (d)(5) (automatic log-off), (d)(6)(emergency access), and (d)(7) (end-user device encryption).	For each applicable P&S certification criterion not certified for approach 1, there must be system documentation sufficiently detailed to enable integration such that the Health IT Module has implemented service interfaces for each applicable privacy and security certification criterion that enable the Health IT Module to access external services necessary to meet the privacy and security certification criterion.
§ 170.315(b)	§ 170.315(d)(1) through (d)(3) and (d)(5) through (d)(8) (integrity).	
§ 170.315(c)	§ 170.315(d)(1) through (d)(3).	
§ 170.315(e)	§ 170.315(d)(1) through (d)(3), (d)(5), and (d)(7).	
§ 170.315(f)	§ 170.315(d)(1) through (d)(3) and (d)(7).	
§ 170.315(h)	§ 170.315(d)(1) through (d)(3).	
§ 170.315(i)	§ 170.315(d)(1) through (d)(3) and (d)(5) through (d)(8).	

To illustrate approach 1 of privacy and security certification, if a Health IT Module is presented for certification to § 170.315(a)(5) (''demographics''), then the Health IT Module must also be certified to § 170.315(d)(1) through (7). We refer readers to Appendix A of this proposed rule for a listing of the P&S certification requirements for each 2015 Edition criterion under approach 1.

Because we have explicitly proposed which P&S certification criteria would be applicable to the associated criteria adopted in each regulatory text ''first level paragraph'' category and have also proposed approach 2, we have not proposed to permit the 2011 Edition policy of allowing for a criterion to be met through documentation that the criterion is inapplicable or would be technically infeasible for the Health IT Module to meet.

We seek comment on the overall clarity and feasibility of this approach.

2. Design and Performance (§ 170.315(g))

We propose to revise § 170.550 to add paragraph (g), which would require ONC–ACBs to certify Health IT Modules to certain proposed certification criteria under § 170.315(g). We propose to require ONC–ACBs to certify Health IT Modules to § 170.315(g)(3) (safety-enhanced design) and § 170.315(g)(6) (Consolidated CDA creation performance) consistent with the requirements included in these criteria. Paragraph (g) also includes a requirement for ONC–ACBs to certify all Health IT Modules presented for certification to the 2015 Edition to § 170.315(g)(4) (quality system management) and (g)(8) (accessibility-centered design). The proposed certification requirements for § 170.315(g)(3) and (4) maintain the policy approach established with certification to the 2014 Edition (see § 170.550(f)(2) and (3)), which ensures Health IT Modules, as applicable, are certified to these specific safety and quality certification criteria. The proposed certification requirements for § 170.315(g)(6) is associated with the new ''Consolidated CDA creation performance'' criterion we have proposed for the 2015 Edition and discuss in more detail in section III.A.3 of this preamble. Again, the requirement is similarly designed to ensure that Health IT Modules (with Consolidated CDA creation capabilities within their scope) are also certified to the ''Consolidated CDA creation performance'' criterion. The proposed certification requirements for § 170.315(g)(8) is associated with the new ''accessibility-centered design'' criterion we have proposed for the 2015 Edition and discuss in more detail in section III.A.3 of this preamble. This criterion and approach to certification is patterned after the 2014 Edition ''quality system management'' criterion.

D. Principles of Proper Conduct for ONC–ACBs

1. ''In-the-Field'' Surveillance and Maintenance of Certification

We propose to adopt new requirements for ''in-the-field'' surveillance under the ONC Health IT Certification Program. Our proposal would build on ONC–ACBs' existing surveillance responsibilities by requiring ONC–ACBs to initiate in-the-field surveillance of certified Complete EHRs and certified Health IT Modules in certain circumstances and in accordance with certain standards and procedures described below. Our proposal would also clarify ONC–ACBs' responsibilities for requiring certified Health IT Module and certified Complete EHR developers to take corrective action in instances where the technology fails to conform to the requirements of its certification. We believe these proposed requirements would promote greater consistency, transparency, and rigor in the surveillance of certified capabilities in the field. They would also provide ONC–ACBs, health IT developers, and users of certified health IT subject to surveillance with greater clarity and predictability regarding this important aspect of the ONC Health IT Certification Program.

Our proposal focuses on ONC–ACBs' responsibilities for conducting surveillance ''in the field.'' In-the-field surveillance is already a requirement of the ONC Health IT Certification Program [231] and is among the most

[231] We explicitly recognized an ''in-the-field surveillance'' requirement in the Proposed Establishment of Certification Programs for Health Information Technology; Proposed Rule, 75 FR 11328 (Mar 10, 2010), wherein we proposed that an ONC–ACB would be required to ''evaluate and reevaluate previously certified Complete EHRs and/or EHR Modules to determine whether [they] continued to perform in an acceptable, if not the same, manner *in the field* as they had performed when they were certified.'' 75 FR 11349 (emphasis added). We finalized this requirement in the Establishment of the Permanent Certification for Health Information Technology; Final Rule, 76 FR 1262 (Jan. 7, 2011) (hereinafter ''PCP Final Rule''). Subsequently, we issued initial and annual guidance to ONC–ACBs clarifying our interpretation of the requirements for in-the-field surveillance under the ONC HIT Certification Program, the preparation and submission of ONC–ACBs' annual surveillance plans, and the reporting of surveillance results to the National Coordinator on an annual basis. *See* ONC HIT Certification Program Guidance #13–01 (July 2013), available at *http://www.healthit.gov/sites/default/files/onc-acb_2013annualsurveillanceguidance_final_0.pdf; see also* ONC HIT Certification Program Guidance #14–

important responsibilities with which an ONC–ACB is charged. It is rooted in the need to provide assurance to purchasers, implementers, and users that certified Complete EHRs and certified Health IT Modules not only meet the requirements of certification in a controlled testing environment but will continue to do so when implemented and used in a production environment. This basic assurance protects the integrity of the ONC Health IT Certification Program and federal health IT investments by enabling individuals to rely upon certifications issued on behalf of ONC to select appropriate technologies and capabilities; identify potential implementation or performance issues; and implement certified health IT in a predictable, reliable, and successful manner.[232] The need to evaluate certified health IT in the field is particularly important for capabilities related to interoperability, patient safety, and privacy and security, which present special implementation challenges, complexities, or risks.[233]

Recognizing that in-the-field surveillance presents technical, operational, and other challenges, we have previously avoided prescribing specific requirements in this area; instead we have provided guidance to ONC–ACBs and encouraged them to develop and refine their own approaches to surveillance. We continue to regard such flexibility as important for minimizing the burden of surveillance on all stakeholders and ensuring that ONC–ACBs' approaches to surveillance reflect their unique expertise and judgment. However, we also believe that establishing certain minimum expectations and procedures for in-the-field surveillance could provide ONC–ACBs as well as health IT developers and users with greater clarity and predictability regarding this important aspect of the ONC Health IT Certification Program. Accordingly, we propose the following additional requirements for in-the-field surveillance under the ONC Health IT Certification Program.

''In-The-Field Surveillance'' Defined

Our proposal explicitly defines in-the-field surveillance to mean an ONC–ACB's assessment of whether a certified Complete EHR or certified Health IT Module to which it has issued a certification continues to conform to the certification's requirements once implemented and in use in the field. This assessment would, by definition, require the ONC–ACB to assess the certified Complete EHR or certified Health IT Module's capabilities in a production environment. The assessment of a capability would be based on the use of the capability with protected health information (PHI) unless the use of test data would provide an equivalent assessment of the capability and were specifically approved by the National Coordinator.[234]

The following hypothetical scenarios illustrate our proposed approach.

- *Scenario 1:* An ONC–ACB initiates in-the-field surveillance for a certified Health IT Module for the medication list certification criterion (proposed at 45 CFR 170.315(a)(8)). An ONC–ACB would then assess this capability at several locations at which the certified Health IT Module has been implemented. The ONC–ACB would assess whether the implemented capability can electronically record, change, and access one or more patients' active medication lists and medication histories as required by the certification criterion.
- *Scenario 2:* An ONC–ACB initiates in-the-field surveillance for a certified Health IT Module's transitions of care capability and one or more applicable transport certification criteria (proposed at 45 CFR 170.315(b)(1) and (h), respectively). During this surveillance, the ONC–ACB would assess these capabilities at several locations at which the certified Health IT Module is implemented to determine whether these certified capabilities perform in compliance with the applicable certification criteria.
- *Scenario 3:* An ONC–ACB initiates in-the-field surveillance for a certified Health IT Module related to the data portability criterion adopted at 45 CFR 170.314(b)(7). Again, the ONC–ACB would need to assess at several locations at which the Health IT Module is implemented whether the certified Health IT Module's data portability capability performed in compliance with the certification criterion.

As these scenarios illustrate, an ONC–ACB's evaluation of health IT in the field must focus on compliance with one or more certification criteria to which a Complete EHR or Health IT Module is certified. Such compliance must be assessed in the production environment in which the Complete EHR or Health IT Module is actually *implemented and used.*

Because certified Complete EHRs and certified Health IT Modules will be integrated with other systems, processes, and people, we acknowledge that the unique circumstances and contexts in which a certified Complete EHR or certified Health IT Module operates could impact an ONC–ACB's ability to assess whether it continues to perform in compliance with adopted certification criteria once it has been implemented and in use. For example, if during in-the-field surveillance an ONC–ACB observed that the certified capability did not perform in a compliant manner, the ONC–ACB would need to determine whether the failure was the result of a problem with the certified capability or, alternatively, whether the failure was caused entirely by other factors beyond the scope of certification, such as a configuration or implementation issue (for which the user was primarily responsible) or the failure of a third-party technology or service over which the health IT developer had limited or no control.

Further, we recognize that the assessment of a certified Complete EHR or certified Health IT Module in a production environment would require ONC–ACBs to employ different methodologies than testing and certification in a controlled environment. Given the additional factors and complexities described above, there could be situations in which an in-person site visit is the best or perhaps the only reliable means of evaluating whether health IT, as implemented in the field, conforms to the requirements of its certification. However, in general, we expect that ONC–ACBs should be able to effectively assess certified capabilities ''in the

01 (July 2014), available at *http://www.healthit.gov/sites/default/files/onc-acb_cy15annualsurveillanceguidance.pdf.*

[232] *See, e.g., FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework* (April 2014) (draft for public comment) (hereinafter ''FDASIA Report''), available at *http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf,* at § 5.3.2 (''For the consumer, ONC certification provides purchasing clarity and assurance that the certified EHR product meets certain criteria and/or functions in a certain way.'')

[233] *See, e.g., FDASIA Report, supra,* at section 5.2.1 (''Errors in communication due to inadequate interoperability, such as the transmission of test results inaccurately or for the wrong patient, do occur and can lead to patient harm.''); ONC HIT Certification Program Guidance #13–01, supra, at 3–4 (prioritizing surveillance for safety-related capabilities); *Health IT Safety Plan, supra,* at 14 (discussing incorporation of health IT safety in post-market surveillance of certified EHR technology).

[234] In consultation with the Office for Civil Rights, we have clarified that under the ''health oversight agency'' exception of the HIPAA Privacy Rule, a healthcare provider would be permitted to disclose protected health information (PHI) to an ONC–ACB during the course of authorized in-the-field surveillance activities, without patient authorization and without a business associate agreement. *See* ONC Regulation FAQ #45 [12–13–045–1], available at *http://www.healthit.gov/policy-researchers-implementers/45-question-12-13-045.*

field'' using other remote methods that would not involve in-person site visits. We believe that such methods may be less intrusive for health care providers, less costly or burdensome for ONC–ACBs, or offer other benefits. Therefore, we request comment on these and other approaches to in-the-field surveillance, on ways to minimize the burden and costs of in-the-field surveillance for ONC–ACBs and health care providers, and on appropriate industry standards or best practices that we should consider adopting to provide ONC–ACBs with consistent, objective, and reliable methods for conducting these evaluations.

Duty To Initiate In-The-Field Surveillance

In addition to defining in-the-field surveillance, this proposal would require ONC–ACBs to initiate in-the-field surveillance in at least two sets of circumstances. These two separate requirements—which we refer to as ''reactive'' and ''randomized'' in-the-field surveillance—are discussed in detail below. Together they would implement sections 7.9.2 and 7.9.3 of ISO/IEC 17065 (the standard to which ONC–ACBs are accredited under the ONC HIT Certification Program), which provide that surveillance ''shall include periodic surveillance . . . to ensure ongoing validity of the demonstration of fulfilment of [] requirements.'' [235] As such, the requirements would become part of the ''certification scheme'' for purposes of ISO/IEC 17065 and would therefore be directly enforceable by the ONC–AA, which is responsible for accrediting ONC–ACBs and verifying their conformance to ISO/IEC 17065 and other program requirements.

Reactive Surveillance

To satisfy the proposed ''reactive'' surveillance requirement, an ONC–ACB would be required to initiate in-the-field surveillance whenever it becomes aware of facts or circumstances that call into question a certified Complete EHR or certified Health IT Module's continued conformance to the requirements of its certification. This reactive surveillance requirement aligns with ONC–ACBs' existing annual surveillance plans, which should specify how an ONC–ACB will ''[s]ystematically obtain and synthesize feedback from users of [health IT] that the ONC–ACB has certified to determine if certain capabilities should be evaluated with the [health IT] developer or with the user in the field, or both.'' [236] We anticipate that such feedback would include (although not be limited to) complaints received from existing and prospective users and implementers of the Complete EHRs and Health IT Modules the ONC–ACB has certified.

We clarify that the receipt of a single complaint would not automatically trigger an ONC–ACB's duty to initiate in-the-field surveillance. In general, an ONC–ACB would be required to consider and weigh the volume, substance, and credibility of complaints received against the type and extent of the alleged non-conformance, in light of the ONC–ACB's expertise and experience with the particular capabilities, health IT, and certification criteria at issue.

We also propose as part of ''reactive'' surveillance that an ONC–ACB must consider the impact and effect of the disclosures made by a Complete EHR or Health IT Module developer on the product's continued conformance to adopted certification criteria. We have proposed this additional review because we believe there are additional factors and circumstances that an ONC–ACB will be unable to assess at the time the health IT was initially certified based on tests completed by the developer in a controlled environment. For example, the ONC–ACB may determine that while a health IT developer's Complete EHR or Health IT Module demonstrated it could perform a required capability in a controlled environment, users in the field cannot reasonably access or use the capability because the health IT developer does not make the capability available; substantially restricts or limits its use; or has not disclosed known material information about the implementation or use of the capability. These and other practices, such as those discussed in our proposal ''Transparency and Disclosure Requirements'' below, could substantially interfere with the performance of certified capabilities in the field and creates a substantial risk that existing or prospective users will encounter problems implementing the capability in a manner consistent with a Complete EHR or Health IT Module's certification. As a result, we have proposed that as part of ''reactive'' surveillance ONC–ACBs evaluate the disclosures in connection with, and in the context of, the certified capability/capabilities under surveillance to gain a full understanding of the way in which the product performs in the field.

We clarify our expectation that ONC–ACBs could render a certified Complete EHR or certified Health IT Module non-conformant to the certification criteria in instances where the developer does not make the capability available; substantially restricts or limits its use; or has not disclosed known material information about the implementation or use of the capability. We also note that we expect ONC–ACBs to give considerable weight to complaints or other indications that a developer has failed meet the disclosure requirements of § 170.523(k)(1).

Consistent with current practice, we expect that the National Coordinator will continue to prioritize certain certification criteria for purposes of surveillance. For example, certification criteria may be prioritized based on the special implementation challenges or risks associated with certain capabilities, especially those related to interoperability, patient safety, and privacy and security. ONC–ACBs would be required to give special scrutiny to complaints about capabilities or disclosures related to these prioritized certification criteria. If an ONC–ACB detected a pattern or trend of such complaints, it would be required to initiate in-the-field surveillance to investigate the complaints and the extent of any non-conformance with the requirements of a certified Complete EHR or certified Health IT Module's certification.

Finally, for the reasons discussed earlier in this proposal and immediately below in our proposal ''Transparency and Disclosure Requirements,'' during reactive surveillance of a certified Complete EHR or Health IT Module in the field, an ONC–ACB would need to verify that the health IT developer has satisfied the mandatory disclosure requirements currently and proposed a § 170.523(k)(1), as applicable, for the certification criteria that are the subject of the ONC–ACB's surveillance.

Randomized Surveillance

Separate from the reactive surveillance described above, we also propose to require ONC–ACBs to conduct ''randomized'' surveillance of the Complete EHRs and Health IT Modules they have certified. We believe randomized surveillance will serve two important purposes: First, it will enable ONC–ACBs to identify nonconformities that are difficult to detect through complaint-based or other reactive forms of surveillance. Second, it will enable ONC–ACBs to detect patterns of non-conformance that indicate a more widespread or recurring problem requiring a more comprehensive

[235] ISO/IEC 17065:2012, available at *http://www.iso.org/iso/catalogue_detail.htm?csnumber=46568.*

[236] ONC HIT Certification Program Guidance #13–01, supra, at 3.

corrective action plan, as discussed below. For these reasons, we believe that randomized surveillance will complement reactive surveillance and strengthen the overall surveillance of certified health IT under the ONC Health IT Certification Program.

Under our proposal, an ONC–ACB would be required to conduct randomized surveillance of prioritized certification criteria (as described in the context of reactive surveillance earlier in this proposal). Focusing on these prioritized certification criteria would maximize the impact and minimize any associated costs or burdens of randomized surveillance. For the same reason, ONC–ACBs would be required to not select certified Complete EHRs and certified Health IT Modules that were selected for randomized surveillance at any time within the preceding twelve months. [237]

To satisfy the proposed randomized surveillance requirement, an ONC–ACB would be required during each calendar year to randomly select at least 10% of the Complete EHRs and Health IT Modules to which it has issued a certification. For each certified Complete EHR or certified Health IT Module selected, the ONC–ACB would initiate in-the-field surveillance at the lesser of 10 or 5% of locations at which the Complete EHR or Health IT Module is implemented and in use in the field.

- *Example:* A Health IT Module is in use at 1,000 locations. Five percent of 1,000 locations equals 50 locations, which is greater than 10 locations. Therefore, the ONC–ACB must evaluate the Health IT Module at a minimum of 10 locations.
- *Example:* A Health IT Module is in use at 100 locations. Five percent of 100 locations equals 5 locations, which is less than 10 locations. Therefore the ONC–ACB must evaluate the Health IT Module at a minimum of 5 locations.

The locations would need to be selected at random by the ONC–ACB from a list of all locations at which the certified Complete EHR or certified Health IT Module is implemented. Where practicable, the sample would need to reflect a diversity of practice types, sizes, settings, and locales.

Similar to reactive surveillance, if in the course of randomized surveillance an ONC–ACB finds that a certified Complete EHR or certified Health IT Module is non-conformant at one or more locations at which surveillance takes place, the ONC–ACB must take appropriate action with the health IT developer, consistent with the ONC–ACB's accreditation, to remedy the nonconformity.

In addition to addressing individual, potentially one-off, nonconformities, an ONC–ACB would also be required to evaluate the overall results of any certified Complete EHR or certified Health IT Module that is subjected to randomized surveillance. If the ONC–ACB finds a pattern of nonconformity—defined as a failure to demonstrate conformance to any prioritized certification criterion at 20% or more of the locations surveilled—the ONC–ACB would regard these results as deficient and would need to require the health IT developer to submit a corrective action plan to address the apparent widespread or recurring issue. Upon making such determination, an ONC–ACB would be required to contact the health IT developer and require that it submit a proposed corrective action plan to the ONC–ACB. The corrective action plan would be required to include, at a minimum, for each certification criterion or required disclosure for which the health IT was deemed deficient:

- A description of the identified deficiencies;
- an assessment of how widespread or isolated the identified deficiencies may be;
- how the developer will address the identified conformance deficiencies in general and at the locations under which surveillance occurred; and
- the timeframe under which corrective action will be completed.

The ONC–ACB would require the health IT developer to submit a proposed corrective action plan to the ONC–ACB within 30 days of the date that the developer was notified by the ONC–ACB of the deficiency or deficiencies above. In general, ONC–ACBs would be responsible for prescribing the required form and content of corrective action plans, consistent with the general elements required above, and for developing specific procedures for the submission and approval of corrective action plans. ONC may also issue guidance to ensure consistency across ONC–ACBs corrective action procedures.

Consistent with an ONC–ACB's accreditation and procedures for suspending a certification, an ONC–ACB would be permitted to initiate certification suspension procedures for a Complete EHR or Health IT Module if the heath IT developer thereof:

- Does not submit a proposed corrective action plan to the ONC–ACB within 30 days of being notified of its deficient surveillance results;
- does not comply with the ONC–ACB's directions for addressing any aspects of the proposed corrective action plan that do not meet the requirements of the ONC–ACB or the ONC Health IT Certification Program; or
- does not complete an approved corrective action plan within 6 months of approval of the plan by the ONC–ACB.

Following the suspension of a certified Complete EHR or certified Health IT Module's certification for the reasons above, an ONC–ACB would be permitted to initiate certification termination procedures for the Complete EHR or Health IT Module (consistent with its accreditation to ISO/IEC 17065 and procedures for terminating a certification) should the developer not complete the actions necessary to reinstate the suspended certification.

Reporting of Surveillance Results

Under our proposal, ONC–ACBs would be required to report the results of in-the-field surveillance to the National Coordinator on at least a quarterly basis. This requirement would reduce the time between when surveillance is initiated and when results are submitted to ONC. Currently under the ONC Health IT Certification Program, ONC–ACBs are not required to submit surveillance results for as long as 14 months after initiating in-the-field surveillance—a significant limitation in our ability to be responsive, including providing relevant information to stakeholders.

Upon requiring a corrective action plan for a certified Complete EHR or certified Health IT Module, an ONC–ACB would be required to report the corrective action plan and related data to the publicly accessible open data CHPL, as detailed below in our proposal ''Open Data Certified Health IT Product List (CHPL).'' The purpose of this reporting requirement, as described in that proposal, would be to ensure that health IT users, implementers, and purchasers are alerted to potential conformance issues in a timely and effective manner, consistent with the patient safety, program integrity, and transparency objectives described subsequently in this proposed rule.

To implement the new requirements for in-the-field surveillance outlined in this proposal, we propose to add § 170.556 (In-the-field surveillance and

[237] This screening requirement would apply only for the purpose of randomized surveillance. The ONC–ACB would still be expected to initiate reactive and other surveillance, including in-the-field surveillance, as necessary to ensure that the Complete EHRs and Health IT Modules it has certified continue to perform in an acceptable manner and meet all certification program requirements.

maintenance of certification for health IT). We would also amend § 170.503 (ONC–AA Ongoing Responsibilities) and § 170.523 (ONC–ACB Principles of Proper Conduct) consistent with the requirements described in this proposal and the related proposals ''Transparency and Disclosure Requirements'' and ''Open Data Certified Health IT Product List (CHPL)'' below. The requirements would provide a floor only, and would in no way limit an ONC–ACB's ability or responsibility to conduct additional surveillance, including in-the-field surveillance, according to the requirements of its accreditation and the ONC Health IT Certification Program. As we have done in the past, we would continue to give ONC–ACBs substantial flexibility and discretion to decide how to implement these requirements as part of their overall approach to surveillance. ONC–ACBs would continue to describe their surveillance programs in their annual surveillance plans, which must be submitted to the National Coordinator prior to the covered calendar year surveillance period. We would also continue to provide annual surveillance guidance to ONC–ACBs, and other guidance or programmatic direction as needed.

At the time of this proposed rule, ONC–ACBs have submitted their annual surveillance plans for calendar year 2015, which include their existing approaches and methodologies for randomized surveillance. To minimize disruption to ONC–ACBs' current surveillance activities, we propose to phase in the requirements proposed at § 170.556(c) for randomized surveillance. As such, the randomized surveillance requirements would become effective beginning January 1, 2016, enabling ONC–ACBs to implement these new requirements in their next annual surveillance plans and incorporate additional guidance and clarification from ONC and the ONC–AA. All other new requirements for in-the-field surveillance—*i.e.,* the requirements proposed at § 170.556(a), (b), and (d)—would be effective immediately; we would expect ONC–ACBs to implement these requirements within 3 months of the effective date of a subsequent final rule. We request comment on whether this timeline and plan for implementation is appropriate and on ways to minimize disruption and ensure that the requirements and purpose of this proposal are timely and effectively achieved.

2. Transparency and Disclosure Requirements

We propose to revise the principles of proper conduct for ONC–ACBs in order to provide for greater and more effective disclosure by health IT developers of certain types of limitations and additional types of costs that could interfere with the ability to implement or use health IT in a manner consistent with its certification. We believe that these additional disclosure requirements are necessary to ensure that existing and potential users and implementers of certified health IT are fully informed about these implementation considerations that accompany capabilities certified under the ONC Health IT Certification Program.

In the 2014 Edition final rule, we adopted new ''price transparency'' requirements that require ONC–ACBs to ensure that health IT developers include—on their Web sites and in all marketing materials, communications, and other assertions related to certified health IT—any ''additional types of costs'' that an EP, eligible hospital, or CAH would pay to implement certified health IT capabilities in order to meet meaningful use objectives and measures (§ 170.523(k)(1)(iii)).[238] We stated that there is value in requiring ONC–ACBs to ensure that developers are transparent about the types of costs associated with certified health IT and that such transparency could provide greater purchasing clarity to EPs, eligible hospitals, and CAHs (77 FR 54274). In regard to purchasing clarity, we further stated that this disclosure requirement could help prevent purchasers from being surprised by additional costs beyond those associated with the adoption and implementation of capabilities certified as part of their certified health IT (77 FR 54275). With this requirement and other transparency requirements under § 170.523(k)(1), we have sought to mitigate potential confusion in the marketplace and reduce the risk that consumers will encounter unexpected difficulties in the implementation and use of certified health IT.

Notwithstanding these modest disclosure requirements, many health IT consumers still have limited access to certain types of information necessary to accurately assess the potential costs, benefits, limitations, and trade-offs of alternative technologies and solutions.[239] This is especially true for small health care providers and other individuals and organizations who may not have the time, resources, or expertise to conduct extensive market research.[240] Health care and health IT industry participants and observers describe a marketplace in certified health IT products and services that is largely opaque and in which consumers often lack up-front information about the products and services they purchase or license. For example, the American Medical Association (AMA) has expressed concern on behalf of its provider members about ''the lack of transparency in EHR contracts,'' which ''may be unclear or fail to itemize specific expenses'' associated with certified health IT capabilities.[241] The

[238] 77 FR 54273–75. For example, under our current disclosure requirements, if health IT is certified to the ''view, download, and transmit to 3rd party'' certification criterion, and an EP would be expected to pay an ''ongoing'' monthly service fee to the technology developer for it to host/administer this capability in order for the EP to meet the correlated meaningful use objective and measure, the existence of this potential ''ongoing'' cost (though not the actual amount or ''dollar value'' of the cost itself) would need to be disclosed by the health IT developer. As another example, a Health IT Module certified to the public health electronic lab reporting certification criterion (§ 170.314(f)(4)) would be able to create a valid HL7 message for electronic submission. However, for the purposes of achieving meaningful use a hospital may be expected to pay their technology developer a separate ''one-time'' and/or ''ongoing'' interface development and configuration fee to establish connectivity between their certified Health IT Module and a public health authority. In such a situation, the potential costs of the interface development and configuration fee would need to be disclosed (though, again, the developer would not be required to disclose the actual ''dollar amount'' of the fee). A final example would be where a health IT developer charges a ''one-time'' fee to integrate its certified health IT with a hospital's other certified technology or a health information exchange organization. Again, just like the other examples, the potential for this fee (but not the ''dollar amount'' itself) would need to be disclosed by the technology developer. Building off these examples, we said that a health IT developer could meet the disclosure requirements by disclosing: 1) the type(s) of additional cost; and 2) to what the cost is attributed. In reference to the first example above, we stated that a developer could meet our price transparency requirement by disclosing that ''an additional ongoing fee may apply to implement XYZ online patient service.'' In situations where the same types of cost apply to different services, we stated that listing each as part of one sentence would be acceptable, such as ''a one-time fee is required to establish interfaces for reporting to immunization registries, cancer registries, and public health agencies.''

[239] *See, e.g.,* Jodi G. Daniel & Karson Mahler, *Promoting Competition to Achieve Our Health IT and Health Care Goals* (Oct. 7, 2014), *http://www.healthit.gov/buzz-blog/health-information-exchange-2/promoting-competition-achieve-healthit-health-care-goals/.*

[240] *See, e.g.,* Kelly Devers, Arnav Shah, and Fredric Blavin, *How Local Context Affects Providers' Adoption and Use of Interoperable Health Information Technology: Case Study Evidence from Four Communities in 2012 (Round One)* (2014), at 7 (describing significant challenges faced by smaller providers dealing with certified EHR vendors, including ''understanding vendor contracts that were very complex.'')

[241] FTC Workshop, Submission #00151 on behalf of the American Medical Association (April 30,

AMA further noted that while ONC has taken steps to promote greater contract transparency, these efforts have fallen short, ''leaving broad discretion and uncertainty'' in the marketplace for certified health IT products.[242]

Other observers have described practices that may interfere with the performance of certified health IT capabilities in ways that are not obvious to consumers at the time they purchase or license technology or services. For example, some health IT contracts may restrict a health care provider's ability to use data contained within an EHR[243] require health care provider staff to complete costly developer-imposed training and accreditation programs before they are allowed to extract patient data; or impose ''access and use agreements'' that restrict a provider's ability to ''engage a third party to assist with extracting and using data to benefit patients . . . .''[244] Some developers also purportedly charge ''additional fees to allow providers to extract patient data from their systems, even though the marginal cost of providing that data is small.[245] In addition, as discussed elsewhere in this proposed rule, Congress has expressed concern that some health IT developers of certified health IT may be engaging in business practices that block health information exchange and thereby frustrate congressional intent, devalue taxpayer investments in health IT, and make health IT less valuable and more burdensome for eligible hospitals and eligible providers to use.[246]

We do not assume that examples cited above are typical or widespread. Yet it must be acknowledged that even ONC has but limited visibility into developers' business practices and cannot reliably assess the extent to which such practices are occurring or the degree to which they may be interfering with the successful implementation and use of certified health IT. That acknowledgement alone should be a sufficient indication of the need to require greater transparency in the marketplace.[247]

The prevailing lack of transparency raises several specific and serious concerns. Most importantly, health IT developers not disclosing known material limitations or additional types of costs associated with the implementation or use of certified health IT creates a substantial risk that existing or prospective users will encounter problems implementing the capabilities of the health IT in a manner consistent with its certification. This in turn diminishes the reliability of certifications issued under the ONC Health IT Certification Program. Moreover, inadequate or incomplete information about health IT products and services distorts the marketplace for certified health IT, for without reliable information consumers cannot accurately estimate costs and assess capabilities in order to effectively compare technologies and choose appropriate solutions for their individual circumstances or needs.[248] Poor health IT purchasing decisions increase the likelihood of downstream implementation challenges and, ultimately, reduced opportunities to use health IT to improve health and health care. Finally, consumers who purchase or license inappropriate or suboptimal technologies may find it difficult to switch to superior alternatives due to the often significant financial and other resources they have already invested in implementation, training, integration with other IT systems, new clinical and administrative processes, and the many other costs and organizational changes associated with implementing health IT. When providers become ''locked in'' to technologies or solutions that do not meet their needs or the needs of their patients, health IT developers may have fewer incentives to innovate and compete on those aspects of health IT that these consumers most value.

For all of these reasons, we propose to revise the principles of proper conduct for ONC–ACBs in order to supplement and strengthen our existing transparency and disclosure requirements under the ONC Health IT Certification Program. As currently set forth in § 170.523(k), ONC–ACBs must require health IT developers to disclose conspicuously on their Web sites and in all marketing materials, communications statements, and other assertions related to certified health IT any additional types of costs[249] that an EP, eligible hospital, or CAH would pay to implement certified health IT to meet meaningful use objectives and measures. We propose to carry forward and expand these requirements as follows.

First, we would no longer limit health IT developers' disclosure obligations to the scope of the EHR Incentive Programs. In the context of our proposals in this proposed rule to make the ONC Health IT Certification Program open and accessible to more types of health IT and to health IT that support various care and practice settings beyond the EHR Incentive Programs, we believe that disclosure requirements should go beyond a link to the EHR Incentive Programs. Consumers are increasingly seeking to leverage certified health IT for a wide range of uses beyond the EHR Incentive Programs, such as to support care coordination with other types of health care providers as part of new quality improvement initiatives and public and private sector value-based payment programs. These consumers of certified health IT need reliable information associated with implementing and using health IT for all of these uses, not just those that are tied to a meaningful use objective or measure. Likewise, as the ONC Health IT Certification Program begins to focus on supporting these new users and uses, it will be important to ensure that certification is meaningful and that surveillance is effective for all certified health IT and capabilities, not just those

2014), available at *http://www.ftc.gov/system/files/documents/public_comments/2014/04/00151–89996.pdf* (accessed Dec. 19, 2014).

[242] *Id.*

[243] FTC Workshop, Submission #00187 on behalf of the Advisory Board Company (April 30, 2014), available at *http://www.ftc.gov/system/files/documents/public_comments/2014/04/00187-89979.pdf* (accessed Dec. 19, 2014).

[244] *Id.*

[245] FTC Workshop, Submission #00045 on behalf of the Health IT Now Coalition (March 10, 2014), available at *http://www.ftc.gov/system/files/documents/public_comments/2014/03/00045-88879.pdf* (accessed Dec. 19, 2014).

[246] 160 Cong. Rec. H9047, H9839 (daily ed. Dec. 11, 2014) (see explanatory statement submitted by Rep. Rogers, chairman of the House Committee on Appropriations, regarding the Consolidated and Further Continuing Appropriations Act, 2015).

[247] We recognize that there is value in encouraging developers to experiment, innovate, and compete to deliver products and services that consumers demand and also to price and distribute such products and services in ways that consumers find attractive and that meet the needs of individual customers. Our proposal to require greater transparency in developers' business practices is intended not to limit but to promote such price and non-price innovation and competition by providing individuals who purchase or license certified health IT with access to basic information necessary to make informed decisions in the marketplace.

[248] *Compare* American Academy of Family Physicians, *Understanding EHR Contracting and Pricing, http://www.aafp.org/practice-management/health-it/product/contracting-pricing.html* (accessed Dec 7, 2014) (noting that there are ''many different ways of pricing EHR software'' and that to ''compare 'apples to apples'" potential purchasers need to consider many variables when selecting an EHR) *with* FTC Workshop, Submission #00151 on behalf of the American Medical Association (April 30, 2014) (expressing concern about ''lack of transparency in EHR vendor contracts'' and ''broad discretion and uncertainty'' despite ONC efforts to promote greater transparency).

[249] Costs vary widely across different developers, products, and services. They may include but are not limited to the cost of purchasing or licensing necessary equipment and software; installing, configuring, maintaining, and updating technology; training staff and integrating technology into clinical workflows; securing and backing up data; licensing information or services used in conjunction with technology; and establishing interfaces or connectivity to other IT systems. Costs may also be incurred on a ''one time'' or on a ''recurring'' or ''ongoing'' basis.

that that are directly tied to the EHR Incentive Programs. For these reasons, we would require ONC–ACBs to ensure that developers disclose any ''additional types of costs'' that a user may incur in order to implement or use capabilities of certified health IT, whether to demonstrate meaningful use objectives or measures or for any other purpose within the scope of the health IT's certification.

Second, the important reasons we have described above for requiring greater transparency and disclosure convince us that we must move beyond our current focus on identifying additional types of costs and consider other factors that may similarly interfere with a user's ability to successfully implement certified health IT. In particular, the failure to disclose material information about limitations associated with certified health IT creates a substantial risk that current or prospective users will encounter problems implementing certified health IT in a manner consistent with its certification. From the perspective of both ONC and the consumer, therefore, the disclosure of this information is no less important than the disclosure of information about additional types of costs. Accordingly, we propose to add this additional category of information to those which a health IT developer must disclose.

Third, to ensure that these disclosure requirements serve their intended purpose, we propose that developers' disclosures be broader and provide greater detail than is currently required. In contrast with our current price transparency requirement, which requires disclosure only of additional types of costs that a user ''would pay'' to implement certain capabilities, our proposal would require health IT developers to be more proactive in identifying the kinds of limitations and additional types of costs that a user *may* pay or encounter in order to achieve any use within the scope of a Complete EHR or Health IT Module's certification. For example, we expect that health IT developers would disclose any additional types of costs or limitations that may be based on potential conditions applicable to the user or options available to the user. This would be different than the current ''would pay'' requirement that focuses on more definitive circumstances. We believe that it is reasonable to require health IT developers to identify this information because they are uniquely familiar with the costs and limitations of their own products and services and possess sophisticated technical knowledge related to the implementation and use of health IT in a variety of settings in which their products are services are deployed.

Health IT developers would therefore be required to provide, in plain language, a detailed description of any material information about limitations that a purchaser may encounter and additional types of costs that a user may be required to pay in the course of implementing or using capabilities to achieve any use within the scope of the its certification. Such information would be ''material'' (and its disclosure therefore required) if the failure to disclose it could substantially interfere with the ability of a user or prospective user to implement certified health IT in a manner consistent with its certification.

To illustrate our expectations as to the types of information that health IT developers would be required to disclose, we provide the following list of types of limitations and additional types of costs that would always be ''material'' and required to be disclosed. We seek comment on whether we should revise or add to the types of information delineated below, including whether we should require the disclosure of more specific cost structures (*e.g.,* the cost structure of a health IT developer's for sending transitions of care summaries, including all relevant factors—*e.g.,* volume transmissions, geography, interfaces, and exchange partner technology).

- Additional types of costs or fees (whether fixed, recurring, transaction-based, or otherwise) imposed by a developer (or any third-party from whom the developer purchases, licenses, or obtains any technology, products, or services in connection with its certified health IT) to purchase, license, implement, maintain, upgrade, use, or otherwise enable and support the use of capabilities to which health IT is certified; or in connection with any data generated in the course of using any capability to which health IT is certified.
- Limitations, whether by contract or otherwise, on the use of any capability to which technology is certified for any purpose within the scope of the technology's certification; or in connection with any data generated in the course of using any capability to which health IT is certified.
- Limitations, including but not limited to technical or practical limitations of technology or its capabilities, that could prevent or impair the successful implementation, configuration, customization, maintenance, support, or use of any capabilities to which technology is certified; or that could prevent or limit the use, exchange, or portability of any data generated in the course of using any capability to which technology is certified.

Because this proposal would significantly expand a health IT developer's existing disclosure obligations, we further clarify our expectations regarding what a health IT developer would and would not be required to disclose. A health IT developer would not be required to disclose specific prices or price information. The health IT developer would be required, however, to describe with particularity the nature and magnitude of any additional types of costs, providing sufficient detail from which a person could arrive at a reasonably accurate estimation of what the likely costs might be, given the person's circumstances and intended use of the capabilities within the certified health IT. For example, if a health IT developer charged a fee every time a user wished to send a transition of care summary record to another user of certified health IT, the health IT developer would be required to fully disclose not only the existence of the fee but the circumstances in which it would apply. The health IT developer would also be required to provide additional information to assist the user in realistically estimating what the cost would be to use the transitions of care capability. The health IT developer could satisfy this requirement by providing data illustrating that there are levels of costs for different types of users (*e.g.,* users who send a ''low,'' ''medium,'' or ''high'' number of summary of care records per month). Alternatively, the health IT developer could indicate that for most (*e.g.,* nine out of every ten) of its users, transaction fees represent less than 1% of a user's total monthly service costs. Other methods of disclosure would also suffice, provided they were similarly calculated and likely to inform.

Health IT developers would not be required to disclose trade secrets or intellectual property. Similar to the disclosure of information about additional types of costs, health IT developers could describe other types of limitations in terms that protect their intellectual property interests and trade secrets. Generalized assertions of ''proprietary information'' would not immunize a developer, however, from a finding by an ONC–ACB that the developer failed to disclose known material information.

Health IT developers would not be required to disclose information of which they are not and could not

reasonably be aware. In particular, we recognize that health IT functions in combination with many third party technologies and services whose specific costs/limitations may be difficult for a health IT developer to precisely predict or ascertain. Local implementation factors and other individual circumstances also vary substantially among customers and impact the cost and complexity of implementing certified health IT. In addition, the costs of upgrading health IT to meet new regulatory requirements or compliance timelines, which are subject to change, may make some particular types of additional costs especially difficult to forecast. While we do not expect health IT developers to account for every conceivable cost or implementation hurdle that a customer may encounter in order to successfully implement and use the capabilities of a developer's certified health IT, we believe it reasonable to assume that health IT developers are experts in their own products and services and possess sophisticated technical knowledge related to the implementation and use of health IT in a variety of settings in which their products are used. Through their accumulated experience developing and providing health IT solutions to their customers, health IT developers should over time become familiar with the types of costs and limitations that most users encounter, and should be able to describe these in sufficient detail so as to provide potential customers with the information they need to make informed purchasing and implementation decisions. We also believe that it is reasonable to expect that a health IT developer would provide a detailed description of any additional considerations that a customer should be aware of in order to reliably estimate the resources needed to purchase the certified health IT and arrive at a realistic expectation of the product's capabilities and performance in the field, to the extent that the health IT developer has knowledge of the customer's circumstances and based on its range of experience (including with other customers).

We propose one additional aspect that we believe will complement the mandatory disclosure requirements set forth in this proposal. In addition to requiring health IT developers to disclose known material information about their certified health IT, an ONC–ACB would be required to obtain a voluntary public attestation from every health IT developer to which it issues or has at any previous time issued a certification for any edition of certified health IT. The attestation would take the form of a written ''pledge'' by the health IT developer to be transparent with regard to the information it is required to disclose under the ONC Health IT Certification Program. Specifically, the health IT developer would be required to attest that, in addition to disclosing such information via its public Web site, marketing materials, communications statements, and other assertions related to certified health IT, it will voluntarily provide this information to: (1) Customers, prior to providing any certified health IT or related product or service (including subsequent updates, add-ons, or additional products or services to be provided during the course of an on-going contract); (2) prospective customers (*i.e.,* persons who request or receive a quotation, estimate, or other similar marketing or promotional material); and (3) other persons who request such information.

To be clear, this attestation would not broaden or change the types of information that a health IT developer would be required to disclose as a condition of certification, nor the persons to whom such information would have to be disclosed. While all health IT developers would be required to make the attestation, their adherence to it would be strictly voluntary, and an ONC–ACB would continue to hold health IT developers only to the mandatory disclosure requirements already described above in this proposal and proposed at § 170.523(k)(1).

Although the attestation would not establish any new regulatory disclosure obligations for health IT developers, it would create a powerful incentive for health IT developers to go beyond what is strictly required of them by regulation and to be more transparent about their health IT products, services, and business practices. The attestation would accomplish this goal by publicly committing health IT developers to make a good faith effort to ensure that consumers actually receive the information that developers are required to disclose at such times and in such a manner as is likely to be useful in informing their health IT purchasing or licensing, implementation, and other decisions.

In particular, health IT developers would be required to attest publicly that they will provide information about their certified health IT to any person who requests it. This would empower not only existing or prospective customers but all consumers and their representatives (*e.g.,* providers' professional associations) to approach developers directly and request information that is most relevant to consumers' health IT purchasing or licensing, and implementation decisions. We believe that as a result consumers will come to expect greater transparency from health IT developers in general, and that developers, having publicly attested that they will provide this information, will have a stronger interest in doing so in order to protect their reputations. Moreover, health IT developers who are the most transparent and provide the most meaningful information about their products and services will be able to differentiate themselves from their competitors, creating additional incentives for other developers to be more transparent.

Attestation will, by encouraging greater interaction between health IT developers and all consumers, provide important feedback to developers about the types of information that consumers find important, and which are therefore likely to be material for purposes of health IT developers' mandatory disclosure obligations under the ONC Health IT Certification Program. For example, requests for information and other feedback from consumers may alert a health IT developer to the fact that it has failed to disclose (or to disclose with sufficient specificity) material information about a particular limitation or additional type of cost associated with its certified health IT. By encouraging consumers to make such inquiries, the proposed attestation requirement will assist health IT developers in meeting their disclosure obligations.

Overall, we believe these proposed requirements will enable more transparency in the marketplace for certified health IT, provide consumers with greater and more ready access to information relevant to their health IT planning, purchasing, and implementation decisions, and reduce the risk of implementation problems and surprise described in this proposal.

3. Open Data Certified Health IT Product List (CHPL)

In the initial rulemaking that we used to establish the Temporary Certification Program, we indicated that the National Coordinator intended to make a master CHPL of all Complete EHRs and EHR Modules tested and certified by ONC–ATCBs available on the ONC Web site and that the CHPL would be a public service and would be a single, aggregate source of all the certified product information ONC–ATCBs provide to the National Coordinator (75 FR 36170). Since 2010, we have maintained the CHPL and as the ONC Health IT Certification Program has matured,

ONC–ACBs have continued to report the products and information about the products they have certified to ONC for listing on the CHPL.

As part of the 2014 Edition final rule (77 FR 54271), we required additional transparency in the ONC Health IT Certification Program in the form of a hyperlink that ONC–ACBs needed to maintain that would enable the public to access the test results that the ONC–ACB used as the basis for issuing a certification. In the time post-final rule, the NVLAP Accredited Testing Laboratories (ATLs) and ONC–ACBs worked together to develop a standard test results summary template for consistent data presentation and use throughout the ONC Health IT Certification Program. For all 2014 Edition products certified under the ONC Health IT Certification Program, the test result summary is accessible and can be found as part of the product's detailed information page on the CHPL Web page.

The test result summary includes granular detail from ATLs about the testing performed, including, among other information: The certification criteria tested; the test procedure, test data, and test tool versions used during testing for each certification criterion; instances where optional portions of certification criteria were tested; and which standard was used for testing when a certification criterion allowed for more than one standard to be used to meet the certification criterion. The test result summary also includes the user-centered design information and summative tests results applicable to a product in cases where it was required to meet the ''safety-enhanced design'' certification criterion (§ 170.314(g)(3)) in order to ultimately be certified.

Multiple stakeholders have commented to us that while the availability of the test report summary and the addition detail it contains is beneficial, its location on the CHPL and its overall accessibility as a PDF makes it difficult to use for any kind of product analysis. In response to this feedback and our overall vision to efficiently administer the CHPL in the future, we intend to convert the CHPL in its current form to an open data file represented in both XML and JSON and with accompanying API functionality. We estimate that this conversion along with the future additional data collection we have proposed for 2015 Edition certifications will occur over the next 12 to 18 months.

To complement this conversion, we propose to require ONC–ACBs to report an expanded set of information to ONC for inclusion in the open data file that would make up the CHPL. Specifically, we propose to revise § 170.523(f) to move the current (f) to (f)(2) and to create a new paragraph (f)(1) that would require ONC–ACBs upon issuing a 2015 Edition (or any subsequent edition certification) to report on the same data elements they report to ONC under § 170.523(f), the information contained in the publicly available test report, and additional data. The data that would be required is as follows:

- The Health IT Module developer name; product name; product version; developer Web site, physical address, email, phone number, and contact name;
- The ONC–ACB Web site, physical address, email, phone number, and contact name, contact function/title;
- The ATL Web site, physical address, email, phone number, and contact name, contact function/title;
- Location and means by which the testing was conducted (*e.g.,* remotely with developer at its headquarters location);
- The date(s) the Health IT Module was tested;
- The date the Health IT Module was certified;
- The unique certification number or other specific product identification;
- The certification criterion or criteria to which the Health IT Module has been certified, including the test procedure and test data versions used, test tool version used, and whether any test data was altered (*i.e.,* a yes/no) and for what purpose;
- The way in which each required privacy and security criterion was addressed for the purposes of certification (note: this is proposed to track the privacy and security certification proposal for Health IT Modules);
- The standard or mapping used to meet the quality management system certification criterion;
- The standard(s) or lack thereof used to meet the accessibility-centered design certification criterion;
- *Where applicable,* the hyperlink to access an API's documentation and terms of use;
- *Where applicable,* which certification criteria were gap certified;
- *Where applicable,* if a certification issued was a result of an inherited certified status request;
- *Where applicable,* the clinical quality measures to which the Health IT Module has been certified;
- *Where applicable,* any additional software a Health IT Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary;
- *Where applicable,* the standard(s) used to meet a certification criterion where more than one is permitted;
- *Where applicable,* any optional capabilities within a certification criterion to which the Health IT Module was tested and certified;
- *Where applicable,* and for each applicable certification criterion, all of the information required to be submitted by Health IT Module developers to meet the safety-enhanced design certification criterion (note: This would include each user-centered design element required to be reported at a granular level (*e.g.,* task success/failure)); and
- *Where applicable,* for each instance in which a Health IT Module failed to conform to its certification and for which a corrective action plan was instituted under § 170.556:
  - The specific certification criterion or certification program requirement (*e.g.,* required disclosure) to which the health IT failed to conform as determined by the ONC–ACB;
  - the dates surveillance was initiated and when available, completed;
  - the results of the surveillance (pass rate for each criterion);
  - the number of sites that were used in surveillance;
  - the date corrective action began;
  - when available, the date corrective action ended;
  - a summary of the deficiency or deficiencies identified by the ONC–ACB as the basis for its determination of non-conformance; and
  - when available, the developer's explanation of the deficiency or deficiencies identified by the ONC–ACB as the basis for its determination of non-conformance.

Consistent with ONC–ACBs' current reporting practice required by § 170.523(f), ONC–ACBs would be required to submit the additional data listed above no less frequently than weekly. Because this expanded list of data would largely subsume the data included in the test results summary, we would no longer require for 2015 Edition and subsequent edition certifications that ONC–ACBs provide a publicly accessible hyperlink to the test results used to certify a Health IT Module.

The last category of data above would be reportable for Complete EHRs and Health IT Modules that have been designated for corrective action as described in our proposal "'In-the-field' Surveillance and Maintenance of Certification'' above. Under that proposal, an ONC–ACB would be required to initiate a corrective action plan for a Complete EHR or Health IT

Module when randomized in-the-field surveillance reveals a pattern of non-conformance to any prioritized certification criterion. Under this Open Data CHPL proposal, the initiation of corrective action would trigger the duty to report the surveillance-related information specified in the last category above for inclusion in the open data file. This reporting requirement would be separate from and in addition to the ''rolling'' (*i.e.,* at least quarterly) reporting of all surveillance results described in our in-the-field surveillance proposal referenced above. The purpose of this separate reporting requirement would be to ensure that health IT users, implementers, and purchasers are alerted to potential conformance issues in a timely and effective manner, consistent with the patient safety, program integrity, and transparency objectives described in this proposed rule. By incorporating data on health IT that has failed surveillance in the open data file, such information would be updated and available to the public at least weekly. Combined with the API functionality described above, such data could also be used more effectively by patient safety, consumer, and other organizations to analyze and disseminate information about product safety and performance.

Our rationale with respect to the reporting of data for health IT that has failed surveillance applies to all, and not only 2015 Edition, certified health IT. Accordingly, we propose to revise new § 170.523(f)(2) (formerly § 170.523(f)) so as to also require the reporting of this surveillance-related data for health IT certified to the 2014 Edition.

In submitting this data related to surveillance of certified health IT, ONC–ACBs would be required to exclude any information that would identify any user or location that participated in or was subject to surveillance (as currently required for ONC–ACBs' annual surveillance results reported to the ONC).

None of the reporting requirements above would require (or authorize) an ONC–ACB to submit or disclose health IT developer's proprietary business information or trade secrets. ONC–ACBs would be required to implement appropriate safeguards to ensure that any proprietary business information or trade secrets of the health IT developer the ONC–ACB might encounter during the course of its surveillance activities would be kept confidential by the ONC–ACB and protected from disclosure. With respect to the safety-enhanced-design data, as stated in our proposal for the 2015 Edition ''safety-enhanced design'' certification criterion (section III.A.3 of this preamble), we do not expect health IT developers to include proprietary information in the submission of summative usability test results to ONC–ACBs. Accordingly, ONC–ACBs would not be required and should take care not to submit proprietary information to ONC for inclusion in the open data file. Similarly, with respect to the reporting of surveillance information for health IT for which corrective action has been initiated, an ONC–ACB would be able to meet the requirement to report a summary of the deficiencies leading to its determination that health IT no longer conforms to the requirements of its certification without disclosing information that the ONC–ACB believes could be proprietary or expose it to liability. Should we adopt this proposal, we would provide additional guidance to ONC–ACBs regarding the particular format of the data required to be submitted to the open data file.

While we recognize that this additional data places a new reporting burden on ONC–ACBs, we believe that the benefit to the public of having all of this data about product certification in granular detail far outweighs the administrative burden it will take to report this information. Further, depending on the certification scope sought some of this data will not need to be collected by ONC–ACBs or will be in hand for subsequent issued certifications. We seek public comment on whether we have omitted any additional data generated during the testing and certification process or the surveillance process that would be useful to the public.

Consistent with these proposals, we also propose to make a conforming modification to 45 CFR 170.523(k)(1)(ii) which currently cross references § 170.523(f) to cross reference proposed paragraph (f)(2) for 2014 Edition certifications and an equivalent set of data (minus the test results summary) in paragraph (f)(1) for 2015 Edition and subsequent certifications.

4. Records Retention

We propose to change the records retention requirement in § 170.523(g) in two ways. We propose to require that ONC–ACBs retain all records related to the certification of Complete EHRs and/or Health IT Module(s) (including EHR Modules) for a minimum of six years instead of five years as currently required. This proposed revision would make certification records available longer, which may be necessary for HHS programs' purposes, such as evaluations our audits. To illustrate, certification to the 2014 Edition began in early 2013 and CMS proposes in the EHR Incentive Programs Stage 3 proposed rule, published elsewhere in this issue of the **Federal Register**, to permit the use of health IT certified to the 2014 Edition through 2017. With attestation taking place in 2018, records may need to be available for a minimum of six years. In addition, a six-year records retention requirement aligns with current accreditation standards within the industry. We also propose that records of certifications performed under the ONC Health IT Certification Program must be available to HHS upon request during the six-year period that a record is retained. We believe this would help clarify the availability of certification records for agencies (*e.g.,* CMS) and authorities (*e.g.,* the Office of Inspector General) within HHS.

5. Complaints Reporting

We propose that ONC–ACBs provide ONC (the National Coordinator) with a list of complaints received on a quarterly basis. We propose that ONC–ACBs indicate in their submission how many complaints were received, the nature or substance of the complaint, and the type of complainant (*e.g.,* type of provider, health IT developer, etc.). We believe this information will provide further insight into potential concerns with certified health IT or the ONC Health IT Certification Program and give ONC a better ability to identify trends or issues that may require action including notification of the public. We propose to include this new requirement in § 170.523(n).

6. Adaptations and Updates of Certified Health IT

We propose a new principle of proper conduct (PoPC) that would serve to benefit ONC–ACBs as well as all stakeholders interested in the ONC Health IT Certification Program and the health IT certified under the program. We propose to require that ONC–ACBs obtain monthly reports from health IT developers regarding their certified health IT. Specifically, we propose to require that ONC–ACBs obtain a record of all adaptations and updates, including changes to user-facing aspects, made to certified health IT (*i.e.,* Complete EHRs and certified Health IT Modules), on a monthly basis each calendar year. We request comment on whether we should require even more frequent reporting.

This new PoPC would apply for all certified Complete EHRs and certified Health IT Modules (which includes ''EHR Modules'') to the 2014 Edition and all certified Health IT Modules to

the 2015 Edition. The PoPC would become effective with a subsequent final rule and we would expect ONC–ACBs to begin complying with the PoPC at the beginning of the first full calendar month that is at least 30 days after the effective date of the final rule. For example, if a final rule became effective on September 6, 2015, then the first full calendar month would be November 2015. In this instance and others, there may be no record to obtain from some health IT developers because their Complete EHRs and Health IT Modules may have been recently certified and they may not have yet created any adaptations or made any updates. We would, however, expect that a health IT developer would still provide a ''record'' indicating that no adaptations had been created and that no updates had occurred to its ONC–ACB for its certified health IT.

We would not expect the information in these records to be reported to ONC and listed on the CHPL. Rather, in weighing the need for ONC–ACBs to properly manage the certifications they issue versus the additional burden a regulatory scheme of ''check-ins'' and potential re-testing/certification for every adaptation and update, we determined that the best course of action would be to provide awareness to ONC–ACBs on adaptations and updates made to technologies they certified. By doing so, we believe ONC–ACBs would be able to make informed decisions when conducting surveillance of certified Complete EHRs and certified Health IT Modules. For example, if an ONC–ACB became aware that a certified Health IT Module had been updated 10 or more times in a month (which could be common with cloud-based products), resulted in 6 adaptations over three months, or had its user-facing aspects altered in an apparent significant way, then an ONC–ACB may want to conduct surveillance on that certified Health IT Module. Overall, we believe our proposed approach protects the integrity of certified health IT and promotes safety and security of certified health IT in a way that seeks to minimizes burden for health IT developers.

E. ''Decertification'' of Health IT—Request for Comment

In the explanatory statement [250] accompanying Public Law 113–235 (Consolidated and Further Continuing Appropriations Act, 2015) the Congress urged ONC to use its certification program to ensure certified electronic health record technology (CEHRT) provides value to eligible hospitals, eligible providers and taxpayers. It also stated that ONC should use its authority to certify only those products that clearly meet current meaningful use program standards and that do not block health information exchange. Further, it stated that ONC should take steps to ''decertify'' products that proactively block the sharing of information.

This proposed rule takes certain steps to support the certification of health IT that meets relevant program standards and permits the unrestricted use of certified capabilities that facilitate health information exchange (*see* the ''In-The-Field Surveillance and Maintenance of Certification'' and ''Transparency and Disclosure Requirements'' proposals in section IV.D of this preamble). We believe, however, that additional rulemaking would be necessary to implement any approach that would include ONC appropriating an ONC–ACB's delegated authority to issue and terminate a certification, including establishing new program requirements and processes by which ONC or an ONC–ACB would have the grounds to terminate an issued certification. Any such rulemaking would need to, at a minimum, address the circumstances, due process, and remedies for the termination of an issued certification. Given that Congress also requested the HITPC to consider and submit a report to them on the challenges and barriers to interoperability within the year,[251] we believe it is premature to include such proposals in this rulemaking. We do, however, solicit public comment on the circumstances, due process, remedies, and other factors that we should consider regarding the termination of a certification. In preparing comments in response to this solicitation, we ask commenters to keep in mind all parties involved, including ONC–ACBs, health IT developers, and consumers (including those providers that participate in the EHR Incentives Programs). Additionally, to help inform commenters, the following provides a brief background of the ONC Health IT Certification Program and examples of the complexities and potential impacts associated with terminating a certification.

Section 3001(c)(5) of the Public Health Service Act (PHSA) provides the National Coordinator with the authority to establish a certification program or programs for the voluntary certification of health information technology.[252] Specifically, this section requires the National Coordinator, in consultation with the Director of the National Institute of Standards and Technology (NIST), to keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria [253] (*i.e.,* certification criteria adopted by the Secretary under section 3004 of the PHSA). Section 3001(c)(5) also requires that any such certification program(s) must include, as appropriate, testing in accordance with section 13201(b) of the HITECH Act, which requires that with respect to the development of standards and implementation specifications, the Director of NIST support the establishment of a conformance testing infrastructure, including the development of technical test beds.

In developing the ONC Health IT Certification Program, ONC consulted with NIST and created the program structure based on industry best practice. This structure includes the use of two separate accreditation bodies: (1) An accreditor that evaluates the competency of a health IT testing laboratory to operate a testing program in accordance with international standards; and (2) an accreditor that evaluates the competency of a health IT certification body to operate a certification program in accordance with international standards. After a certification body is accredited, it may apply to the National Coordinator to receive authorization to certify health IT on ONC's behalf. Once authorized, we refer to these certification bodies as ONC-Authorized Certification Bodies or ONC–ACBs. The ONC Health IT Certification Program includes a full process by which ONC oversees the operations of ONC–ACBs. It also includes a process for the issuance of certain types of violations as well as a process to revoke an ONC–ACBs authorization to certify health IT on ONC's behalf.[254]

[250] 160 Cong. Rec. H9047, H9839 (daily ed. Dec. 11, 2014) (explanatory statement submitted by Rep. Rogers, chairman of the House Committee on Appropriations, regarding the Consolidated and Further Continuing Appropriations Act, 2015); and *https://www.congress.gov/congressional-record/2014/12/11/house-section/article/H9307-1.*

[251] *https://www.congress.gov/congressional-record/2014/12/11/house-section/article/H9307-1.*

[252] ''health information technology'' is defined in Section 3000(5) to mean ''hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information''.

[253] ''certification criteria'' is defined in Section 3001(c)(5)(B) to mean ''with respect to standards and implementation specifications for health information technology, criteria to establish that the technology meets such standards and implementation specifications.''

[254] See the Permanent Certification Program final rule (76 FR 1262); subpart E, part 170 of title 45;

With respect to ONC–ACBs and the international standard (ISO Guide 65/ ISO 17065) to which they are accredited, they are uniquely positioned and accountable for determining whether a certified product continues to conform to the certification requirements to which the product was certified. If an ONC–ACB can substantiate a non-conformity, either as a result of surveillance or otherwise, the international standard requires that the ONC–ACB consider and decide upon the appropriate action, which could include: (1) The continuation of the certification under specified conditions (*e.g.* increased surveillance); (2) a reduction in the scope of certification to remove nonconforming product variants; (3) suspension of the certification pending remedial action by the developer; or (4) withdrawal/ termination of the certification.[255]

With respect to ONC's role and ability to revoke or terminate an issued certification, ONC's regulations do not address this point directly and have largely deferred, with one exception, to the ONC–ACBs autonomy and delegated authority to effectively administer its certification business. The one exception involves the scenario where ONC revokes an ONC–ACB's authorization due to a ''type-1'' program violation that calls into question the legitimacy of the issued certification (see 45 CFR 170.570). In such an instance, we established a process by which the National Coordinator would review and determine whether an ONC–ACB's misconduct justifies revoking the certification issued to one or more products (76 FR 1297–99).

In general, we believe that it's important for commenters to account for the potentially profound asymmetric impacts revoking a certification could create, especially if based on the business practices (by a health IT developers or their customers) associated with the health IT's use and not necessarily the health IT's performance according to certification requirements. These asymmetric impacts are present in any paradigm in which a certified product is required for compliance with a program (*e.g.,* the use of certified health IT under the Medicare and Medicaid EHR Incentive Programs and Electronic Prescribing of Controlled Substances). To illustrate, the impact of revoking a certification based on a health IT developer's business practice(s) may create a lopsided (and arguably unfair/ inequitable) impact to all those who rely on the certification in order to comply with the legal requirement(s) of a program they are participating in. Additionally, if such a health IT developer's business practice(s) were not universally applied to all customers, the outright removal of a certification could unfairly penalize the health IT developer's other customers who were unaffected by the business practice. Similarly, if the practices of a group of a health IT developer's customers were found to be impeding information exchange, outright revoking the product's certification (for how it was requested to be implemented or configured) could in this case unfairly penalize the health IT developer as well as other ''good actor'' customers and information exchange partners of the developer. We also note that there could be contractual and other legal agreements affected by any action that terminates a certification.

All of the above potential circumstances are meant to highlight for commenters the significant analysis, complexity, and need for root cause determinations that would be necessary to develop and implement a regulatory scheme supporting an equitable certification termination process led or directed by ONC under the ONC Health IT Certification Program. To support justification of such a process based on the blocking of health information exchange, we further solicit comment on examples of health IT certified under the ONC Health IT Certification Program that may have been used in the past, or currently, to proactively block the sharing of health information.

V. Response to Comments

Because of the large number of public comments normally received in response to 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 of that document.

VI. Incorporation by Reference

The Office of the Federal Register has established new requirements for materials (*e.g.,* standards and implementation specifications) that agencies propose to incorporate by reference in the **Federal Register** (79 FR 66267; 1 CFR 51.5(a)). Specifically, § 51.5(a) requires agencies to discuss, in the preamble of a proposed rule, the ways that the materials it proposes to incorporate by reference are reasonably available to interested parties or how it worked to make those materials reasonably available to interested parties; and summarize, in the preamble of the proposed rule, the material it proposes to incorporate by reference.

To make the materials we intend to incorporate by reference reasonably available, we provide a uniform resource locator (URL) for the standards and implementation specifications. In many cases, these standards and implementation specifications are directly accessible through the URL provided. In instances where they are not directly available, we note the steps and requirements necessary to gain access to the standard or implementation specification. In most of these instances, access to the standard or implementation specification can be gained through no-cost (monetary) participation, subscription, or membership with the applicable standards developing organization (SDO) or custodial organization. In a few instances, where noted, access requires a fee or paid membership.

The National Technology Transfer and Advancement Act (NTTAA) of 1995 (15 U.S.C. 3701 *et seq.*) and the Office of Management and Budget (OMB) Circular A–119[256] require the use of, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. The NTTAA and OMB Circular A–119 provide exceptions to selecting only standards developed or adopted by voluntary consensus standards bodies, namely when doing so would be inconsistent with applicable law or otherwise impractical. As discussed in section III of this preamble, we have followed the NTTAA and OMB Circular A–119 in proposing standards and implementation specifications for adoption, including describing any exceptions in the proposed adoption of standards and implementation specifications. Over the years of adopting standards and implementation specifications for certification, we have worked with SDOs, such as HL7, to make the standards we propose to adopt, and subsequently adopt and incorporate by reference in the **Federal Register**, available to interested stakeholders. As described above, this includes making the standards and implementation specifications available

and *http://www.healthit.gov/policy-researchers-implementers/about-onc-hit-certification-program.*

[255] ISO 17065 (§ 170.599(b)(3)). See also § 170.599(a) for general availability of this standard.

[256] *http://www.whitehouse.gov/omb/circulars_a119.*

through no-cost memberships and no-cost subscriptions.

As required by § 51.5(a), we provide summaries of the standards and implementation specifications we propose to adopt and subsequently incorporate by reference in the **Federal Register**. We also provide relevant information about these standards and implementation specifications throughout section III of the preamble. In particular, in relevant instances, we identify differences between currently adopted versions of standards and implementation specifications and proposed versions of standards and implementation specifications.

We have organized the following standards and implementation specifications that we propose to adopt through this rulemaking according to the sections of the Code of Federal Regulation (CFR) in which they would be codified and cross-referenced for associated certification criteria that we propose to adopt in 45 CFR 170.315. We note, in certain instances, we request comment in this proposed rule on multiple standards or implementation specifications that we are considering for adoption *and incorporation by reference* for a particular use case. We include all of these standards and implementation specifications in this section of the preamble.

Transport and Other Protocol Standards—45 CFR 170.202

• *ONC Implementation Guide for Delivery Notification in Direct.*

URL: *http://wiki.directproject.org/file/view/Implementation+Guide+for+Delivery+Notification+in+Direct+v1.0.pdf.* This is a direct link.

Summary: This document provides implementation guidance enabling Security/Trust Agents (STAs) to provide a high level of assurance that a message has arrived at its destination. It also outlines the various exception flows that result in a compromised message delivery and the mitigation actions that should be taken by STAs to provide success and failure notifications to the sending system.

• *Healthcare Provider Directory, Trial Implementation, October 13, 2014.*

URL: *http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_HPD.pdf.* This is a direct link.

Summary: This document introduces the Healthcare Provider Directory (HPD) that supports queries against and management of, health care provider information that may be publicly shared in a directory structure. HPD directory structure is a listing of two categories of health care providers, individual and organizational providers.

Functional Standards—45 CFR 170.204

• *HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. (''Infobutton''), Knowledge Request, Release 2.*

URL: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=208.* Access requires a ''user account'' and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: The Context-aware knowledge retrieval specifications (Infobutton) provide a standard mechanism for clinical information systems to request context-specific clinical knowledge from online resources. Based on the clinical context, which includes characteristics of the patient, provider, care setting, and clinical task, Infobutton(s) anticipates clinicians' and patients' questions and provides automated links to resources that may answer those questions.

• *HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1.*

URL: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=283.* Access requires a ''user account'' and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: Context-aware knowledge retrieval (Infobutton) into clinical information systems help deliver clinical knowledge to the point of care as well as patient-tailored education material. This specification enables the implementation of context-aware knowledge retrieval applications through a Service Oriented Architecture based on the RESTful software architectural style.

• *HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4.*

URL: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=22.* Access requires a ''user account'' and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: Context-aware knowledge retrieval (Infobutton) in clinical information systems help deliver clinical knowledge to the point of care as well as patient-tailored education material. This implementation guide provides a standard mechanism for EHR systems to submit knowledge requests over the HTTP protocol through a standard using a URL format.

• *HL7 Version 3 Standard: Clinical Decision Support Knowledge Artifact Specification, Release 1.2 Draft Standard for Trial Use.*

URL: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=337.* Access requires a ''user account'' and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: The Clinical Decision Support Knowledge Artifact Specification provides guidance on how to specify and implement shareable CDS knowledge artifacts using XML. The scope of the Specification includes event-condition-action rules, order sets, and documentation templates.

• *HL7 Implementation Guide: Decision Support Service, Release 1.1, US Realm, Draft Standard for Trial Use.*

URL: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=334.* Access requires a ''user account'' and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: A Decision Support Service takes in patient data as the input and provides back patient-specific assessments and recommendations. A Decision Support Service facilitates the implementation of CDS capabilities in a scalable manner. This implementation guide defines a Decision Support Service implementation approach that combines the HL7 Decision Support Service Release 2 standard with the HL7 Virtual Medical Record for CDS information model standard to enable the provision of standards-based, interoperable decision support services.

Content Exchange Standards and Implementation Specifications for Exchanging Electronic Health Information—45 CFR 170.205

• *HL7 Implementation Guide for CDA® R2: Quality Reporting Document Architecture—Category I, DSTU Release 2 (US Realm) and Errata (September 2014).*

URL: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35.* Access requires a ''user account'' and a license agreement. There is no monetary cost for a user account and license agreement. The DSTU package must be downloaded in order to access the errata.

Summary: The Quality Reporting Document Architecture (QRDA) is an electronic document format that provides a standard structure with which to report quality measure data to organizations that will analyze and interpret the data. The Implementation Guide is consistent with CDA, and Category I is an individual-patient-level quality report. The September 2014 Errata reflects updates for the implementation of QRDA Category I consistent with the Quality Data Model-

based Health Quality Measures Format Release 2.1, an incremental version of harmonized clinical quality measure and CDS standards.

• *HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.0.*

URL: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=379.* Access requires a ''user account'' and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: The Consolidated CDA (C–CDA) implementation guide contains a library of CDA templates, incorporating and harmonizing previous efforts from HL7, IHE, and Health Information Technology Standards Panel (HITSP). It represents harmonization of the HL7 Health Story guides, HITSP C32, related components of IHE Patient Care Coordination (IHE PCC), and Continuity of Care (CCD). The C–CDA Release 2 implementation guide, in conjunction with the HL7 CDA Release 2 (CDA R2) standard, is to be used for implementing the following CDA documents and header constraints for clinical notes: Care Plan including Home Health Plan of Care, Consultation Note, CCD, Diagnostic Imaging Reports, Discharge Summary, History and Physical, Operative Note, Procedure Note, Progress Note, Referral Note, Transfer Summary, Unstructured Document, and Patient Generated Document (US Realm Header).

• *HL7 Implementation Guide for CDA® Release 2: Additional CDA R2 Templates—Clinical Documents for Payers—Set 1, Release 1—US Realm, Draft Standard for Trial Use.*

URLs: *http://www.hl7.org/special/Committees/claims/index.cfm* and *http://www.hl7.org/participate/online balloting.cfm?ref=nav#nonmember.* This is a direct access link to the most recent publicly available version of the implementation guide. HL7 policy normally requires a paid membership or a ''non-member participation'' fee to access the balloting process of a standard or implementation guide. HL7 has, however, agreed to make current balloted versions of the implementation guide freely available for review during the public comment period of this proposed rule. Access requires a ''user account'' and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: The purpose of the Clinical Documents for Payers—Set 1(CDP1) implementation guide is to provide guidance on a standardized, implementable, interoperable electronic solution to reduce the time and expense related to the exchange of clinical and administrative information between and among providers and payers. This guide describes structured documentation templates that meet requirements for documentation of medical necessity and appropriateness of services to be delivered or that have been delivered in the course of patient care. These document templates are designed for use when the provider needs to exchange more clinical information than is required by the C–CDA R2 document-level templates and/or must indicate why information for specific section-level or entry-level templates is not included.

• *HL7 Implementation Guide for CDA Release 2: Digital Signatures and Delegation of Rights, Release 1.*

URL: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=375.* Access requires a ''user account'' and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: The Digital Signature and Delegation of Rights Implementation Guides provide a standardized method of applying Digital Signatures to CDA documents. The standard provides for multiple signers, signer's declaration of their role, declaration of purpose of the signature, long-term validation of the Digital Signatures and data validation of the signed content.

• *Author of Record Level 1: Implementation Guide.*

URL: *http://wiki.siframework.org/file/view/esMD%20AoR%20Level%201%20Implementation%20Guide%20v5%20FINAL.docx/539084894/esMD%20AoR%20Level%201%20Implementation%20Guide%20v5%20FINAL.docx.* This is a direct link. This implementation guide was developed under the Standards and Interoperability (S&I) Framework.[257]

Summary: The Author of Record Level 1 Implementation Guide utilizes the IHE Document Digital Signature standard and Security Assertion Markup Language (SAML) assertions to support applying digital signatures and delegation of rights information to bundles of documents exchanged over content neutral transports.

• *Provider Profiles Authentication: Registration Implementation Guide.*

URL: *http://wiki.siframework.org/file/view/esMD%20Use%20Case%201%20Implementation%20Guide%20V24%20FINAL.docx/539084920/esMD%20Use%20Case%201%20Implementation%20Guide%20V24%20FINAL.docx.* This is a direct link. This implementation guide was developed under the Standards and Interoperability (S&I) Framework.[258]

Summary: The Provider Profiles Authentication Implementation Guide provides methods for applying digital signatures and delegation of rights information to the most common administrative and clinical transactions, including: ASC X12, CONNECT, Direct, and HL7 V2.

• *HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Draft Standard for Trial Use, Release 2—US Realm.*

URL: *http://www.hl7.org/participate/onlineballoting.cfm?ref=nav#nonmember.* HL7 policy normally requires a paid membership or a ''non-member participation'' fee to access the balloting process of a standard or implementation guide. HL7 has, however, agreed to make current balloted versions of the implementation guide freely available for review during the public comment period of this proposed rule. Access requires a ''user account'' and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: The Laboratory Orders Implementation Guide identifies the requirements, specifications, and standards, and provides the implementation guidance for the electronic ordering of laboratory tests in the US Realm. The scope of the Laboratory Orders Interface Use Case includes requirements to enable a particular implementation of an Electronic Health Record System (EHR–S) to use standardized structured data in a defined inter-organizational laboratory transaction. The Use Case requirements are directed at laboratory test orders between an Ambulatory Provider's EHR–S and a Laboratory's Laboratory Information System (LIS). Future versions of this guide may harmonize with existing guides to extend interoperability of laboratory results across care settings, *e.g.,* acute care.

• *HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2, Version 1.2 (eDOS).*

URL: *http://www.hl7.org/participate/online balloting.cfm?ref=nav#nonmember.* HL7 policy normally requires a paid membership or a ''non-member participation'' fee to access the balloting process of a standard or implementation guide. HL7 has, however, agreed to

[257] *http://www.healthit.gov/policy-researchers-implementers/standards-interoperability-si-framework.*

[258] *http://www.healthit.gov/policy-researchers-implementers/standards-interoperability-si-framework.*

make current balloted versions of the implementation guide freely available for review during the public comment period of this proposed rule. Access requires a ''user account'' and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: The focus of the Laboratory Test Compendium Framework is to provide a standardized means of electronically communicating a Laboratory's Directory of Services (eDOS). The content is owned by the sending laboratory for the purpose of being used by the compendium consumer to order laboratory services and to understand the requirements and components of those services. The consumer (and consuming systems) should not modify or delete the content unless instructed to do so by the producer via eDOS updates or some other form of written communication. Adding to the content to provide additional information specific to the consumer's needs such as cross reference to local codes and/or other performing labs, or other information that does not change or conflict with the content of the original information provided by the performing laboratory, is permitted.

• *HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Draft Standard for Trial Use, Release 2—US Realm.*

URL: *http://www.hl7.org/participate/online balloting.cfm?ref=nav#nonmember.* HL7 policy normally requires a paid membership or a ''non-member participation'' fee to access the balloting process of a standard or implementation guide. HL7 has, however, agreed to make current balloted versions of the implementation guide freely available for review during the public comment period of this proposed rule. Access requires a ''user account'' and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: The Laboratory Results Interface (LRI) Implementation Guide identifies the requirements, defines specifications and standards, and provides implementation guidance for electronic reporting of laboratory test results to ambulatory care providers in the US Realm. The scope of the Laboratory Results Interface Use Case includes requirements to enable the incorporation of clinical laboratory test results into an EHR–S as standardized structured data using the defined inter-organizational laboratory transaction. The Use Case requirements are directed at laboratory test results reporting between a LIS and an ambulatory EHR–S in different organizational entities (*e.g.,* different corporate structure, ownership or governance). Future versions of this guide may harmonize with existing guides to extend interoperability of laboratory results across care settings (*e.g.,* acute care).

• *HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability.*

URL: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=301.* Access requires a ''user account'' and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: The HL7 Clinical Genomics Family Health History (Pedigree) Model is a data standard for capturing, within a system, and transmitting family histories between systems. This includes describing a patient's full pedigree (family and familial relationships) with diseases and conditions, and the option to link genetic information and risk analysis. This standard allows EHR/personal health record interoperability.

• *NCPDP Formulary and Benefit Standard Implementation Guide v3.0.*

URL: *http://ncpdp.org/Standards/Standards-Info* and *http://ncpdp.org/?ReturnUrl=%2fmembers%2fStandards-Lookup.aspx.* Access requires completion of a membership application and a paid membership. NCPDP has stated that membership allows NCPDP to provide a forum wherein a diverse membership can develop business solutions, standards, and guidance for promoting information exchanges related to medications, supplies, and services within the health care system through consensus building processes. We note that CMS has already adopted the NCPDP Formulary and Benefit Standard Implementation Guide v3.0 and incorporated it by reference in the **Federal Register** as a standard for electronic prescribing under the voluntary Medicare prescription drug benefit program.[259]

Summary: The NCPDP Formulary and Benefit Standard Implementation Guide provides a standard means for pharmacy benefit payers to communicate formulary and benefit information to prescribers via technology vendor systems. It enables the physician to consider information during the prescribing process to help make an appropriate drug choice for the patient. Compared to v2.1, v3.0 removes some unused information, provides some value clarifications, adds additional RxNorm references to fields, and adds support for text messaging.

• *NCPDP Formulary and Benefit Standard Implementation Guide v4.0.*

URL: *http://ncpdp.org/Standards/Standards-Info* and *http://ncpdp.org/?ReturnUrl=%2fmembers%2fStandards-Lookup.aspx.* Access requires completion of a membership application and a paid membership. NCPDP has stated that membership allows NCPDP to provide a forum wherein a diverse membership can develop business solutions, standards, and guidance for promoting information exchanges related to medications, supplies, and services within the health care system through consensus building processes.

Summary: The NCPDP Formulary and Benefit Standard Implementation Guide provides a standard means for pharmacy benefit payers to communicate formulary and benefit information to prescribers via technology vendor systems. It enables the physician to consider information during the prescribing process to help make an appropriate drug choice for the patient. Compared to v3.0, v4.0 modifies a field size, removes some values, and makes editorial edits to a figure.

• *NCPDP Formulary and Benefit Standard Implementation Guide v4.1.*

URL: *http://ncpdp.org/Standards/Standards-Info* and *http://ncpdp.org/?ReturnUrl=%2fmembers%2fStandards-Lookup.aspx.* Access requires completion of a membership application and a paid membership. NCPDP has stated that membership allows NCPDP to provide a forum wherein a diverse membership can develop business solutions, standards, and guidance for promoting information exchanges related to medications, supplies, and services within the health care system through consensus building processes.

Summary: The NCPDP Formulary and Benefit Standard Implementation Guide provides a standard means for pharmacy benefit payers to communicate formulary and benefit information to prescribers via technology vendor systems. It enables the physician to consider information during the prescribing process to help make an appropriate drug choice for the patient. Compared to v4.0, v4.1 removes files to support electronic Prior Authorization (ePA) transactions since these were added to the NCPDP SCRIPT Standard Implementation Guide v2013011 (January 2013) and later versions, makes typographical corrections, adds a new coverage type for ePA routing, and adds an RxNorm qualifier to some data elements.

[259] 42 CFR 423.160(b)(5)(iii). *http://www.ecfr.gov/cgi-bin/text-idx?SID=776f4d6a1759e7616051 6348d3ca4454&node=se42.3.423_1160&rgn=div8.*

• *NCPDP Formulary and Benefit Standard Implementation Guide v42.*

URL: *http://ncpdp.org/Standards/Standards-Info* and *http://ncpdp.org/?ReturnUrl=%2fmembers%2fStandards-Lookup.aspx.* Access requires completion of a membership application and a paid membership. NCPDP has stated that membership allows NCPDP to provide a forum wherein a diverse membership can develop business solutions, standards, and guidance for promoting information exchanges related to medications, supplies, and services within the health care system through consensus building processes.

Summary: The NCPDP Formulary and Benefit Standard Implementation Guide provides a standard means for pharmacy benefit payers to communicate formulary and benefit information to prescribers via technology vendor systems. It enables the physician to consider information during the prescribing process to help make an appropriate drug choice for the patient. Compared to v4.1, v42 [260] includes changes to reduce the formulary file size, modifies some code lists and values, and revises some fields.

• *NCPDP Telecommunication Standard Implementation Guide vE6.*

URL: *http://ncpdp.org/Standards/Standards-Info* and *http://ncpdp.org/?ReturnUrl=%2fmembers%2fStandards-Lookup.aspx.* Access requires completion of a membership application and a paid membership. NCPDP has stated that membership allows NCPDP to provide a forum wherein a diverse membership can develop business solutions, standards, and guidance for promoting information exchanges related to medications, supplies, and services within the health care system through consensus building processes.

Summary: The Telecommunication Standard was developed to provide a standard format for the electronic submission of third party drug claims. The development of the standard was to accommodate the eligibility verification process at the point-of-sale and to provide a consistent format for electronic claims processing. The Telecommunication Standard includes transactions for eligibility verification, claim and service billing, predetermination of benefits, prior authorization, information reporting, and controlled substance (general and regulated) transaction exchanges.

• *ASC X12 270/271 Health Care Eligibility Benefit Inquiry and Response Implementation Guide.*

URL: *http://store.x12.org/store/healthcare-5010-consolidated-guides.* Access requires either a membership with ASC X12 or the user to purchase a single user or unlimited user license. ASC X12 develops and maintains EDI and CICA standards along with XML standards for a number of sectors, including health care, insurance, transportation, finance, government, and supply chain. ASC X12 has stated that membership allows it to support standards development and participation; meetings, conferences, and educational venues; standards and publications; tools for members; and networking and visibility.

Summary: The Health Care Eligibility/Benefit Inquiry and Information Response Implementation Guide describes the use of the Eligibility, Coverage or Benefit Inquiry (270) Version/Release 005010 transaction set and the Eligibility, Coverage, or Benefit Information (271) Version/Release 005010 transaction set for the following usages: Determine if an Information Source organization, such as an insurance company, has a particular subscriber or dependent on file; and determine the details of health care eligibility and/or benefit information.

• *HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1.*

URL: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=354.* Access requires a ''user account'' and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: This guide supports segmenting clinical records so that protected health information (PHI) can be appropriately shared as may be permitted by privacy policies or regulations.

• *HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5.*

URL: *http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf.* This is a direct link.

Summary: This document represents the collaborative effort of the American Immunization Registry Association and CDC to improve inter-system communication of immunization records. The guide is intended to facilitate exchange of immunization records between different systems.

• *PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent, Ambulatory Care, and Inpatient Settings, Release 2.0.*

URL: *http://www.cdc.gov/phin/library/guides/SyndrSurvMessagGuide2_MessagingGuide_PHN.pdf.* This is a direct link.

Summary: This document represents the collaborative effort of the International Society for Disease Surveillance, CDC, and NIST to specify a national electronic messaging standard that enables disparate health care applications to submit or transmit administrative and clinical data for public health surveillance and response. The scope of the guide is to provide guidelines for sending HL7 v.2.5.1 compliant messages from emergency department, urgent and ambulatory care, and inpatient settings to public health authorities.

• *HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm), Draft Standard for Trial Use R1.1.*

URL: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=329.* Access requires a ''user account'' and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: This guide is the result of collaborative efforts between HL7 and the S&I Laboratory Results Interface Initiative. The guide describes constraints, comments, and elements necessary for laboratory reporting to public health.

• *HL7 Implementation Guide for CDA⊃© Release 2: Reporting to Public Health Cancer Registries From Ambulatory Healthcare Providers, Release 1.*

URL: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=383.* Access requires a ''user account'' and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: As ambulatory health care providers adopt modern EHR systems, the opportunity to automate cancer registry reporting from ambulatory health care provider settings is also increasing and becoming more feasible. This document provides clear and concise specifications for electronic reporting form ambulatory health care provider EHR systems to public health central cancer registries using the HL7 CDA based standards. This document is designed to guide EHR vendors and public health central cancer registries in the implementation of standardized electronic reporting.

• *IHE IT Infrastructure Technical Framework Volume 2b (ITI TF–2b).*

URL: *http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_Rev7–0_Vol2b_FT_2010-08-10.pdf.* This is a direct link.

Summary: This document defines specific implementations of established

[260] Please note a change to the naming convention starting with Version 42.

standards to achieve integration goals that promote appropriate sharing of medical information to support ongoing patient care. The IHE IT Infrastructure Technical Framework identifies a subset of functional components of the health care enterprise, called ''IHE actors,'' and specified their interactions in terms of a set of coordinated, standards-based transactions. Volume 2b corresponds to transactions [ITI–29] through [ITI–57].

• *IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation.*

URL: *http://www.ihe.net/uploadedFiles/Documents/QRPH/IHE_QRPH_Suppl_SDC.pdf.* This is a direct link.

Summary: The Structured Data Capture Content Profile provides specifications to enable an EHR system or other application to retrieve a data capture form and submit data from the completed form. This supplement is based on the work of ONC's S&I Framework Structured Data Capture (SDC) Initiative. The SDC Initiative has developed use cases, identified national standards for the structure of common data elements and form model definition, developed guidance to assist in implementation, and conducted pilots for evaluation of SDC.

• *HL7 FHIR Implementation Guide: Structured Data Capture (SDC).*

URL: *http://hl7.org/implement/standards/FHIR-Develop/sdc.html#SDC.* This is a direct link.

Summary: This implementation guide is intended to support clinical systems in the creation and population of forms with patient-specific data. It defines a mechanism for linking questions in forms to pre-defined data elements to enable systems to automatically populate portions of the form based on existing data, either locally or by invoking an operation on a third-party system. Note that the SDC FHIR Implementation Guide is balloted as comment-only.

• *HL7 Implementation Guide for CDA® Release 2—Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm.*

URL: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=20.* Access requires a ''user account'' and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: This document specifies a standard for electronic submission of health care associated infection reports (HAI) to the National Healthcare Safety Network of the CDC. This document defines the overall approach and method of electronic submission and develops constraints defining specific HAI report types.

• *HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, Draft Standard for Trial Use (December 2014).*

URL: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=385.* Consistent with HL7 policy, non-member access would not be available until April 14, 2015. HL7 has, however, agreed to waive the normal 90-day waiting period and make the implementation guide freely available during the public comment period of this proposed rule. Access requires a ''user account'' and license agreement. There is no monetary cost for a user account and license agreement.

Summary: The HL7 Implementation Guide for CDA Release 2: National Health Care Surveys (NHCS), Release 1—US Realm will provide a standardized format for implementers to submit data to fulfill requirements of the Centers for Disease Control and Prevention/National Center for Health Statistics/National Health Care Surveys. This guide will support automatic extraction of the data from a provider's EHR system or data repository. The data are collected through three surveys of ambulatory care services in the United States: The National Ambulatory Medical Care Survey with information from physicians and two national hospital care surveys: The National Hospital Ambulatory Medical Care Surveys and the National Hospital Care Survey with data from hospital emergency and outpatient departments.

• *NCPDP SCRIPT Implementation Recommendations Version 1.29.*

URL: *http://www.ncpdp.org/NCPDP/media/pdf/SCRIPTImplementationRecommendationsV1-29.pdf.* This is a direct link. The Implementation Recommendations Version 1.29 is available at no monetary cost, but references the NCPDP Structured and Codified Sig Implementation Guide Version 1.2. Access to NCPDP standards requires completion of a membership application and a paid membership. NCPDP has stated that membership allows NCPDP to provide a forum wherein a diverse membership can develop business solutions, standards, and guidance for promoting information exchanges related to medications, supplies, and services within the health care system through consensus building processes.

Summary: This Implementation Recommendations document includes recommendations for implementation of the structured and codified sig format for a subset of component composites that represent the most common Sig segments using NCPDP Structured and Codified Sig Implementation Guide Version 1.2. The recommendations promote consistent and complete prescription transactions of the NCPDP SCRIPT Standard.

Vocabulary Standards for Representing Electronic Health Information—45 CFR 170.207

• *IHTSDO SNOMED CT®, U.S. Edition, September 2014 Release.*

URL: *http://www.nlm.nih.gov/research/umls/Snomed/us_edition.html.* Access requires a user account and license agreement. There is no monetary cost for a user account and license agreement.

Summary: Systemized Nomenclature of Medicine—Clinical Terms (SNOMED CT®) is a comprehensive clinical terminology, originally created by the College of American Pathologists and, as of April 2007, owned, maintained, and distributed by the International Health Terminology Standards Development Organisation. SNOMED CT® improves the recording of information in an EHR system and facilitates better communication, leading to improvements in the quality of care.

• *Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.50, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.*

URL: *http://loinc.org/downloads.* Access requires registration, a user account, and license agreement. There is no monetary cost for registration, a user account, and license agreement.

Summary: LOINC® was initiated in 1994 by the Regenstrief Institute and developed by Regenstrief and the LOINC® committee as a response to the demand for electronic movement of clinical data from laboratories that produce the data to hospitals, provider's offices, and payers who use the data for clinical care and management purposes. The scope of the LOINC® effort includes laboratory and other clinical observations. The LOINC® database facilitates the exchange and pooling of results for clinical care, outcomes management, and research.

• *RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, February 2, 2015 Release.*

URL: *http://www.nlm.nih.gov/research/umls/rxnorm/docs/rxnormfiles.html.* Access requires a user account and license agreement. There is no monetary cost for a user account and license agreement.

Summary: RxNorm provides normalized names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software. By providing links between vocabularies commonly used in pharmacy management and drug interaction software, RxNorm can mediate messages between systems not using the same software and vocabulary. RxNorm now includes the National Drug File—Reference Terminology (NDF–RT) from the Veterans Health Administration, which is used to code clinical drug properties, including mechanism of action, physiologic effect, and therapeutic category.

• *HL7 Standard Code Set CVX—Vaccines Administered, updates through February 2, 2015.*

URL: *http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx.* This is a direct link.

Summary: CDC's National Center of Immunization and Respiratory Diseases developed and maintains HL7 Table 0292, Vaccine Administered (CVX). CVX includes both active and inactive vaccines available in the U.S. CVX codes for inactive vaccines allow transmission of historical immunization records; when paired with a manufacturer (MVX) code, the specific trade named vaccine may be indicated.

• *National Drug Code Directory—Vaccine Codes, updates through January 15, 2015.*

URL: *http://www2a.cdc.gov/vaccines/iis/iisstandards/ndc_tableaccess.asp.* This is a direct access link.

Summary: The Drug Listing Act of 1972 requires registered drug establishments to provide the FDA with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it by commercial distribution. Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which services as the universal product identifier for drugs. This standard is limited to the NDC vaccine codes identified by CDC at the URL provided.

• *HL7 Standard Code Set MVX—Manufacturers of Vaccines Code Set, updates through October 30, 2014.*

URL: *http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=mvx.* This is a direct link.

Summary: CDC's National Center of Immunization and Respiratory Diseases developed and maintains HL7 Table 0227, Manufacturers of Vaccines (MVX). The MVX table includes both active and inactive vaccines available in the U.S. MVX codes allow transmission of historical immunization records. When MVX code is paired with a CVX code, the specific trade named vaccine may be indicated.

• *''Race & Ethnicity—CDC'' code system in the PHIN Vocabulary Access and Distribution System (VADS), Release 3.3.9.*

URL: *https://phinvads.cdc.gov/vads/ViewCodeSystem.action?id=2.16.840.1.113883.6.238.* This is a direct link.

Summary: The Public Health Information Network (PHIN) VADS is a web-based enterprise vocabulary systems for accessing, searching, and distributing vocabularies used within the PHIN. PHIN VADS provides standard vocabularies to CDC and its public health partners in one place. It promotes the use of standards-based vocabulary to support the exchange of consistent information among public health partners.

• *Request for Comments (RFC) 5646.*

URL: *http://www.rfc-editor.org/info/rfc5646.* This is a direct access link.

Summary: RFC 5646 describes the structure, content, construction, and semantics of language tags for use in cases where it is desirable to indicate the language used in an information object. It also describes how to register values for use in language tags and the creation of user-defined extensions for private interchange.

• The Unified Code of Units of Measure, Revision 1.9.

URL: *http://unitsofmeasure.org/trac/.* This is a direct access link. The codes can be viewed in html or xml.

Summary: The Unified Code of Units of Measure is a code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with units.

Standards for Health Information Technology To Protect Electronic Health Information Created, Maintained, and Exchanged—45 CFR 170.210

• *Any encryption algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140–2, October 8, 2014.*

URL: *http://csrc.nist.gov/publications/fips/fips140-2/fips1402annexa.pdf.* This is a direct link.

Summary: Federal Information Processing Standards Publication (FIPS PUB) 140–2, *Security Requirements for Cryptographic Modules,* specifies the security requirements that are to be satisfied by the cryptographic module utilized within a security system protecting sensitive information within computer and telecommunications systems. The standard provides four increasing qualitative levels of security that are intended to cover the wide range of potential applications and environments in which cryptographic modules may be employed.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide 60-day notice in the **Federal Register** and solicit public comment on a proposed collection of information before it is submitted to the Office of Management and Budget for review and approval. In order to fairly evaluate whether an information collection should be approved by the Office of Management and Budget, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency;
2. The accuracy of the agency's estimate of the information collection burden;
3. The quality, utility, and clarity of the information to be collected; and
4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Under the PRA, the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section are to be considered. We explicitly seek, and will consider, public comment on our assumptions as they relate to the PRA requirements summarized in this section. To comment on the collection of information or to obtain copies of the supporting statements and any related forms for the proposed paperwork collections referenced in this section, email your comment or request, including your address and phone number to *Sherette.funncoleman@hhs.gov,* or call the Reports Clearance Office at (202) 690–6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above email address within 60 days.

Abstract

Under the ONC Health IT Certification Program, accreditation organizations that wish to become the ONC-Approved Accreditor (ONC–AA) must submit certain information, organizations that wish to become an

ONC–ACB must submit the information specified by the application requirements, and ONC–ACBs must comply with collection and reporting requirements, records retention requirements, and submit annual surveillance plans and annually report surveillance results.

In the Permanent Certification Program final rule (76 FR 1312–14), we solicited public comment on each of the information collections associated with the requirements described above (and included in regulation at 45 CFR 170.503(b), 170.520, and 170.523(f), (g), and (i), respectively). In the 2014 Edition final rule (77 FR 54275–76), we sought comment on these collection requirements again and finalized an additional requirement at § 170.523(f)(8) for ONC–ACBs to report to ONC a hyperlink with each EHR technology they certify that provides the public with the ability to access the test results used to certify the EHR technology. These collections of information were approved under OMB control number 0955–0013 (previous OMB control number 0990–0378).

As discussed in more detail below, we estimate less than 10 annual respondents for all of the regulatory ''collection of information'' requirements under Part 170 of Title 45, including those previously approved by OMB and proposed in this proposed rule. Accordingly, the regulatory ''collection of information'' requirements under the ONC Health IT Certification Program described in this section are not subject to the PRA under 5 CFR 1320.3(c). We welcome comments on this conclusion and our supporting rationale for this conclusion as recited below. We also set out below proposed revisions to previously approved ''collections of information'' and potential new ''collections of information'' as well as our burden estimates for these ''collections of information.''

We propose to change the records retention requirement in § 170.523(g) from five years to six years. It is our understanding that a six-year records retention requirement aligns with current accreditation standards that ONC–ACBs follow. Therefore, we do not believe there will be any additional burden based on this proposed change.

We propose in § 170.523(o) that ONC–ACBs provide ONC with a list of complaints received on a quarterly basis. We only request that ONC–ACBs indicate in their submission how many complaints were received, the nature or substance of the complaint, and the type of complainant (*e.g.,* type of provider, health IT developer, etc.). Therefore, we believe ONC–ACBs will face little burden in complying with this new proposed requirement.

For regulatory clarity in relation to new proposed ONC–ACB collection and reporting requirements, we have proposed to move all of the current ONC–ACB collection and reporting requirements in § 170.523(f) to § 170.523(f)(2). These collection and reporting requirements are specific to the certification of health IT to the 2014 Edition. We note that we have also proposed to add a data element to the list of collection and reporting requirements for 2014 Edition certifications. The data element is the reporting of any corrective action instituted under the proposed provisions of § 170.556 (see section IV.D.3 of this preamble; see also § 170.523(f)(2)(ix)).

We propose to add a new ONC–ACB collection and reporting requirements for the certification of health IT to the 2015 Edition (and any subsequent edition certification) in § 170.523(f)(1). As proposed for § 170.523(f)(1), ONC–ACBs would be required to report on the same data elements they report to ONC under current § 170.523(f), the information contained in the publicly available test report, and additional data in an open data file format. These collection and reporting requirements are described in more detail in section IV.D.3, titled ''Open Data Certified Health IT Product List (CHPL).'' We do not anticipate any additional burden on ONC–ACBs for reporting similar information for 2015 Edition certifications as they do for 2014 Edition certifications. For the additional data that we propose they report, we believe that burden would be minimal as discussed below.

For the purposes of estimating the additional potential burden for reporting under § 170.523(f)(1) and (2):

- We assume there will be three ONC–ACBs as this is the current number of ONC–ACBs.
- We assume ONC–ACBs will continue to report weekly (*i.e.,* respondents will respond 52 times per year) as is the current practice.
- We assume an equal distribution among ONC–ACBs in certifying Health IT Modules on a weekly basis. As such, based on the number of Complete EHRs and EHR Modules listed on the CHPL at the end of July of 2014 (approximately one and a half years since ONC began certifying 2014 Edition products), we estimate that, on average, each ONC–ACB will report information to ONC on 2015 Edition certifications for 2.5 Health IT Modules per week.
- We expect 2014 Edition certifications to slow upon issuance of a subsequent final rule and estimate that each ONC–ACB will only issue, on average, one 2014 Edition certification per week after a subsequent final rule is effective. Therefore, we have reduced the average burden hours per response to .75 from 1.33 for § 170.523(f)(2). This new average burden hour estimate takes into account any potential ONC–ACB reporting of data associated with the new proposed provisions for corrective action instituted under § 170.556 (see § 170.523(f)(2)(ix)).
- We believe it will take approximately 1.5 hours per week on average to collect and report to ONC the information required for 2015 Edition certifications in § 170.523(f)(1), including the information that goes beyond what is currently collected and reported for 2014 Edition certifications. Our estimate includes a potential wide range of certifications issued for Health IT Modules, including, but not limited to, certifying Health IT Modules to multiple certification criteria and CQMs. Our estimates also take into account that it may take ONC–ACBs more time in the beginning of the collection and reporting processes as they may need to recode their systems to collect and report the new information in an automated manner. Therefore, we believe 1.5 hours represents a reasonable average of the amount of time for an ONC–ACB to collect and report the information proposed under § 170.523(f)(1). Our burden estimate is incorporated into the table below.

As stated above, we anticipate that there will be three ONC–ACBs participating in the ONC Health IT Certification Program as this is the current number of ONC–ACBs. Further, since the establishment of the ONC Health IT Certification Program in 2010, ONC has never had more than six applicants for ONC–ACB or ONC–ATCB status or selected more than six ONC–ACBs or ONC–ATCBs.[261] Therefore, we have aligned the estimated number of respondents for the applicable regulation provisions (*i.e.,* § 170.523(f)(1) and (2), (g), (i), and (o); and § 170.540(c)) with the current number of ONC–ACBs. We have also revised the estimated number of respondents for § 170.503(b) (applicants for ONC-Approved Accreditor (ONC–AA) status) based on past selection processes for the ONC–AA, which have

[261] See also: *http://www.healthit.gov/policy-researchers-implementers/authorized-testing-and-certifications-bodies* and *http://www.healthit.gov/policy-researchers-implementers/certification-bodies-testing-laboratories.*

included no more than two applicants. We have retained the same number of responses per respondent and average burden hours per response for the regulation provisions currently included in OMB control number 0995–0013, except for § 170.523(f) as specified above (now § 170.523(f)(2)). Our estimates for the total burden hours are expressed in the table below.

ESTIMATED ANNUALIZED TOTAL BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
45 CFR 170.503(b)	2	1	1	2
45 CFR 170.520	1	1	1	1
45 CFR 170.523(f)(1)	3	52	1.5	234
45 CFR 170.523(f)(2)	3	52	.75	117
45 CFR 170.523(g)	3	n/a	n/a	n/a
45 CFR 170.523(i)	3	2	1	6
45 CFR 170.523(o)	3	4	1	12
45 CFR 170.540(c)	3	1	1	3
Total burden hours				375

VIII. Regulatory Impact Statement

A. Statement of Need

This proposed rule is being published to adopt the 2015 Edition. Certification criteria and associated standards and implementation specifications would be used to test and certify health IT in order to make it possible for EPs, eligible hospitals, and CAHs to adopt and implement health IT that can be used to meet the CEHRT definition. EPs, eligible hospitals, and CAHs who participate in the EHR Incentive Programs are required by statute to use CEHRT.[262]

The certification criteria and associated standards and implementation specifications would also support the certification of more types of health IT and health IT that supports care and practice settings beyond the scope of the EHR Incentive Programs.

The adoption and implementation of health IT certified to the 2015 Edition promotes interoperability in support of a nationwide health information infrastructure and improves health care quality, safety and efficiency consistent with the goals of the HITECH Act.

B. Overall Impact

We have examined the impact of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011), the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532), and Executive Order 13132 on Federalism (August 4, 1999).

[262] Section 1848(o) of the Social Security Act.

1. Executive Orders 12866 and 13563—Regulatory Planning and Review Analysis

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). OMB has determined that this proposed rule is an economically significant rule as ONC has estimated the costs to develop and prepare health IT to be tested and certified may be greater than $100 million per year. Because of the public interest in this proposed rule, we have prepared an RIA that to the best of our ability presents the costs and benefits of the proposed rule.

a. Costs

This proposed rule proposes the adoption of standards, implementation specifications, and certification criteria that would establish the capabilities that health IT would need to demonstrate to be certified to the 2015 Edition. Our analysis focuses on the direct effects of the provisions of this proposed rule—the costs incurred by health IT developers to develop and prepare health IT to be tested and certified in accordance with the certification criteria (and the standards and implementation specifications they include) adopted by the Secretary. That is, we focus on the technological development and preparation costs necessary for health IT *already certified to the 2014 Edition* to upgrade to the proposed 2015 Edition and for, in limited cases, developing and preparing a new Health IT Module to meet the 2015 Edition. The costs for the testing and certification of health IT to the 2015 Edition were captured in the regulatory impact analysis of the Permanent Certification Program final rule as we discuss in more detail below (VIII.B.1.a.iii ''Testing and Certification Costs for the 2015 Edition''). Because the costs that EPs, eligible hospitals, and CAHs would incur in adopting and implementing (including training, maintenance, and any other ongoing costs) health IT certified to the 2015 Edition is overwhelmingly attributable to CMS's EHR Incentive Programs Stage 3 proposed rule (proposed elsewhere in this issue of the **Federal Register**), and would not be incurred in the absence of such rulemaking, such costs are not within the scope of the analysis of this proposed rule; similarly, any benefits that are contingent upon adoption and implementation would be attributable to CMS's rulemaking.[263] We also note that this proposed rule does not impose the costs cited as compliance costs, but rather as investments which health IT

[263] ONC administers a voluntary certification program that provides no incentives for certification. Therefore, to the extent that providers' implementation and adoption costs are attributable to CMS's rulemaking, health IT developers' preparation and development costs would also be attributable to that rulemaking (because all of the costly activities are, directly or indirectly, incentivized by CMS's proposed payment structure). However, even if CMS's proposed rule were not finalized, a professional organization or other such entity could require or promote certification, thus generating costs and benefits that are attributable to this proposed rule. To avoid giving the misleading impression that such effects equal zero, we present in this RIA a subset of the relevant impacts—a quantification of costs that are incurred by health IT developers and a qualitative discussion of benefits. (The missing portion of the subset is providers' implementation and adoption costs.)

developers voluntarily take on and expect to recover with an appropriate rate of return.

i. Development and Preparation Costs for the 2015 Edition

The development and preparation costs we estimate are derived through a health IT developer per criterion cost. In simple terms, we estimate: (1) How many health developers will prepare and develop products against the proposed certification criteria; (2) how many products they will develop; and (3) what it will likely cost them to develop and prepare those products to meet the proposed certification criteria.

We are not aware of an available *independent* study (*e.g.,* a study capturing the preparation efforts and costs to develop and Health IT Modules to meet the requirements of the 2014 Edition) that we could rely upon as a basis for estimating the efforts and costs required to develop and prepare health IT to meet the 2015 Edition. We welcome comments identifying such a study or on any valid and reliable data upon which we could base our estimates in a subsequent final rule.

Proposed Certification Criteria

We have divided the proposed certification criteria into two tables. One table is for the certification criteria associated with EHR Incentive Programs Stage 3 proposed objectives and measures (''Stage 3 Criteria''). This table also includes certification criteria that are included in conditional certification requirements, such as privacy and security, safety-enhanced design, and quality management system certification criteria as certified Health IT Modules certified to these criteria would likely be used to meet the CEHRT definition under the EHR Incentive Programs. The second table is for all other proposed certification criteria (''Independent Criteria''). We have done this because, based on available data, we can more accurately estimate the number of health IT developers that may develop and prepare Health IT Modules for certification to proposed certification criteria associated with the EHR Incentive Programs.

Health IT Developers

We derive our estimates for the number of health IT developers by beginning with the number of Health IT developers certified to each of the 2014 Edition certification criteria as identified in CHPL data from November 10, 2014. For the Stage 3 Criteria that correspond to 2014 Edition certification criteria, we have reduced the number of Health IT developers by 30% from the number that certified against the 2014 Edition. We have done this because we have found a 22% drop in the number of health IT developers that certified technology against the 2014 Edition versus the 2011 Edition. We believe that as both interoperability requirements increase by edition and certain health IT developers gain more market share through competition and acquisition of other health IT developers, there will be an even greater drop in the number of health IT developers that seek certification to the 2015 Edition. We welcome comments on this assumption.

For the Independent Criteria, we have established a number of health IT developers for all the criteria at 16. We derived this number by taking the lowest number of health IT developers certified to a 2014 Edition certification criteria and reducing that number by 50%. Only 32 health IT developers have certified to the 2014 Edition ''transmission to cancer registries'' certification criterion (§ 170.314(f)(6)) even though it is associated with an EHR Incentive Programs Stage 2 menu objective. The Independent Criteria are not currently associated with the EHR Incentive Programs or other HHS payment programs. Therefore, we estimate that a small number of health IT developers would certify to these criteria (*i.e.,* 50% less than the least amount of health IT developers certified to a certification criterion that supports the EHR Incentive Programs). We welcome comments on our approach to estimating the number of health IT developers for Independent Criteria. We also seek comment on reasons (*e.g.,* use cases) why health IT developers would currently seek certification to these criteria in general or for each proposed criteria.

To note, the estimated number of Health IT developers for each criterion includes any potential new entrants to the market.

Number of Health IT Modules

We estimate 2.5 products per health IT developer for each Stage 3 criterion. We reached this estimate based both on the number of unique [264] certified products listed on the CHPL as of November 10, 2014 divided by the number of health IT developers certified and stakeholder feedback on our Voluntary Edition proposed rule (79 FR 54474). We estimate 1 product for each of the Independent Criteria (60% less). As noted above, the Independent Criteria are not currently associated with the EHR Incentive Programs or other HHS payment programs. Therefore, it is not only unclear how many health IT developers will seek certification to these criteria, but also how many products they would certify to these criteria. We can only assume that the number of products certified by each health IT developer will likely be less than for Stage 3 Criteria. Again, we welcome comments on estimates.

Average Development and Preparation Hours

Our estimated average development hours are based on feedback we received in response to the RIA we completed for on our Voluntary Edition proposed rule and internal estimates for criteria where there is no external data to validly rely upon. As noted in the Voluntary Edition final rule, we have generally used estimates from the Electronic Health Record Association as a basis for our high estimates, where applicable. For the Stage 3 Criteria, we include the development and preparation for 2.5 certified products per health IT developer in the estimated average development and preparation hours. For the Independent Criteria, we have built in an estimate of 60% less overall development and preparation hours due to our assumption that a health IT developer would develop only one product.

As mentioned above, for proposed 2015 Edition certification criteria that have a corresponding 2014 Edition criterion, we estimate only the development and preparation hours to meet the new and revised capabilities included in a proposed criterion.

Health IT Developer Hourly Cost and Cost Range

We have based the effort levels on the hours necessary for a software developer to develop and prepare the health IT for testing and certification. The U.S. Department of Labor, Bureau of Labor Statistics estimates that the median hourly wage for a software developer is $44.55.[265] We have also calculated the costs of an employee's benefits by assuming that an employer expends thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. We have concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. We have rounded up the average software

[264] We attempted to discern how many Complete EHRs and Health IT Modules were used that would not constitute a newer version of the same technology.

[265] *http://www.bls.gov/oes/current/oes151132.htm.*

developer's wage with benefits to $61 per hour.

To calculate our cost estimates for each certification criterion in the tables below, we have multiplied both the average low and average high number of development and preparation hours by $61. For tables 8 and 9, dollar amounts are expressed in 2013 dollars.

For unchanged certification criteria,[266] we have estimated a range of 0–50 hours to account for new entrants in the Stage 3 Criteria table (Table 6) and used 60% less of that estimate in the ''Independent Criteria'' table (Table 7). To illustrate, that would produce a high development hours of 12,700 for the ''medication list'' criterion (item # 7). This likely still overestimates the burden hours of all potential new entrants.

Estimated Health IT Developers and Development Hours Per Criterion

TABLE 6—ESTIMATED HEALTH IT DEVELOPERS AND DEVELOPMENT AND PREPARATION HOURS FOR PROPOSED CERTIFICATION CRITERIA—CRITERIA ASSOCIATED WITH THE EHR INCENTIVE PROGRAMS STAGE 3

[Stage 3 Criteria]

Item No.	CFR text	Certification criterion name	Number of health IT developers who develop product(s) for certification to criterion	Hourly development effort by health IT developer	
				Low Avg	High Avg
1	§ 170.315(a)(1)	CPOE—medications	83.3	0	50
2	§ 170.315(a)(2)	CPOE—laboratory	83.3	1,000	2,000
3	§ 170.315(a)(3)	CPOE—diagnostic imaging	83.3	0	50
4	§ 170.315(a)(4)	DD/DAI Checks for CPOE	242.2	400	800
5	§ 170.315(a)(5)	Demographics	268.8	500	1,000
6	§ 170.315(a)(7)	Problem List	256.9	100	200
7	§ 170.315(a)(8)	Medication List	254.8	0	50
8	§ 170.315(a)(9)	Medication Allergy List	252.7	0	50
9	§ 170.315(a)(10)	Clinical Decision Support	235.2	600	1,200
10	§ 170.315(a)(11)	Drug-formulary and Preferred Drug List Checks.	233.1	310	620
11	§ 170.315(a)(12)	Smoking Status	266.7	100	200
12	§ 170.315(a)(14)	Family Health History	216	100	200
13	§ 170.315(a)(15)	Family Health History—pedigree	24	500	1,200
14	§ 170.315(a)(17)	Patient-specific Education Resources	249.2	600	1,200
15	§ 170.315(a)(19)	Patient Health Information Capture	88.9	500	1,000
16	§ 170.315(a)(20)	Implantable Device List	90	1,100	1,700
17	§ 170.315(b)(1)	Transitions of Care	242.9	1,550	3,100
18	§ 170.315(b)(2)	Clinical Information Reconciliation and Incorporation.	224	600	1,200
19	§ 170.315(b)(3)	Electronic Prescribing	224.7	1,050	2,100
20	§ 170.315(b)(6)	Data Portability	228.9	800	1,600
21	§ 170.315(c)(1)	CQMs—record and export	246.4	200	500
22	§ 170.315(d)(1)	Authentication, Access Control, Authorization.	333.9	0	50
23	§ 170.315(d)(2)	Auditable Events and Tamper-resistance	272.3	0	50
24	§ 170.315(d)(3)	Audit Report(s)	280	0	50
25	§ 170.315(d)(4)	Amendments	243.6	0	50
26	§ 170.315(d)(5)	Automatic Access Time-out	333.9	0	50
27	§ 170.315(d)(6)	Emergency Access	308.7	0	50
28	§ 170.315(d)(7)	End-User Device Encryption	267.4	0	50
29	§ 170.315(d)(8)	Integrity	312.2	0	50
30	§ 170.315(e)(1)	View, Download, and Transmit to 3rd party	256.2	1,000	2,000
31	§ 170.315(e)(2)	Secure Messaging	246.4	0	50
32	§ 170.315(f)(1)	Transmission to Immunization Registries	220.5	680	1,360
33	§ 170.315(f)(2)	Transmission to Public Health Agencies—syndromic surveillance.	213.5	480	960
34	§ 170.315(f)(3)	Transmission to Public Health Agencies—reportable laboratory tests and values/results.	49	520	1,040
35	§ 170.315(f)(4)	Transmission to Cancer Registries	22.4	500	1,000
36	§ 170.315(f)(5)	Transmission to Public Health Agencies—case reporting.	21	500	1,000
37	§ 170.315(f)(6)	Transmission to Public Health Agencies—antimicrobial use and resistance reporting.	21	500	1,000
38	§ 170.315(f)(7)	Transmission to Public Health Agencies—health care surveys.	21	500	1,000
39	§ 170.315(g)(1)	Automated Numerator Recording	113.4	400	800
40	§ 170.315(g)(2)	Automated Measure Calculation	264.6	600	1,200
41	§ 170.315(g)(3)	Safety-enhanced Design	266	300	600

[266] For the purposes of estimating development hours, we are currently characterizing the 2015 Edition ''automatic access time-out'' (§ 170.315(d)(5)) and ''end-user device encryption'' certification criterion (§ 170.315(d)(7)) as unchanged despite clarifying edits to the criteria and updates.

TABLE 6—ESTIMATED HEALTH IT DEVELOPERS AND DEVELOPMENT AND PREPARATION HOURS FOR PROPOSED CERTIFICATION CRITERIA—CRITERIA ASSOCIATED WITH THE EHR INCENTIVE PROGRAMS STAGE 3—Continued

[Stage 3 Criteria]

Item No.	CFR text	Certification criterion name	Number of health IT developers who develop product(s) for certification to criterion	Hourly development effort by health IT developer	
				Low Avg	High Avg
42	§ 170.315(g)(4)	Quality Management System	401.8	400	800
43	§ 170.315(g)(6)	Consolidated CDA Creation Performance	242	400	1,000
44	§ 170.315(g)(7)	Application Access to Common Clinical Data Set.	242	500	1,000
45	§ 170.315(g)(8)	Accessibility-Centered Design	401.8	50	100
46	§ 170.315(h)(1)	Direct Project	140	0	50
47	§ 170.315(h)(2)	Direct Project, Edge Protocol, and XDR/XDM.	70	0	50

TABLE 7—ESTIMATED HEALTH IT DEVELOPERS AND DEVELOPMENT AND PREPARATION HOURS FOR PROPOSED CERTIFICATION CRITERIA—CRITERIA NOT ASSOCIATED WITH THE EHR INCENTIVE PROGRAMS STAGE 3

[“Independent Criteria”]

Item No.	CFR text	Certification criterion name	Number of health IT developers who develop product(s) for certification to criterion	Hourly development effort by health IT developer	
				Low Avg	High Avg
1	§ 170.315(a)(6)	Vital Signs, BMI, and Growth Charts	16	614	922
2	§ 170.315(a)(13)	Image Results	16	0	20
3	§ 170.315(a)(16)	Patient List Creation	16	0	20
4	§ 170.315(a)(18)	Electronic Medication Administration Record	16	0	20
5	§ 170.315(a)(21)	Social, Psychological, and Behavioral Data	16	235	470
6	§ 170.315(a)(22)	Decision Support—knowledge artifact	16	394	788
7	§ 170.315(a)(23)	Decision Support—service	16	229	458
8	§ 170.315(b)(4)	Incorporate Laboratory Tests and Values/Results	16	313	626
9	§ 170.315(b)(5)	Transmission of Laboratory Test Reports	16	360	720
10	§ 170.315(b)(7)	Data Segmentation for Privacy—send	16	450	900
11	§ 170.315(b)(8)	Data Segmentation for Privacy—receive	16	450	900
12	§ 170.315(b)(9)	Care Plan	16	300	500
13	§ 170.315(c)(2)	CQMs—import and calculate	16	0	200
14	§ 170.315(c)(4)	CQMs—filter	16	316	632
15	§ 170.315(d)(9)	Accounting of Disclosures	16	0	20
16	§ 170.315(g)(5)	Accessibility Technology Compatibility	16	800	1,400
17	§ 170.315(h)(3)	SOAP Transport and Security Specification and XDR/XDR for Direct Messaging.	16	0	20
18	§ 170.315(h)(4)	Healthcare Provider Directory—query request	16	120	240
19	§ 170.315(h)(5)	Healthcare Provider Directory—query response	16	120	240
20	§ 170.315(i)(1)	Electronic Submission of Medical Documentation	16	1,000	2,000

Estimated Cost Per Criterion for Health IT Developers

TABLE 8—TOTAL DEVELOPMENT AND PREPARATION COSTS PER CRITERION FOR HEALTH IT DEVELOPERS—CRITERIA ASSOCIATED WITH THE EHR INCENTIVE PROGRAMS STAGE 3

[“Stage 3 Criteria”]

Item No.	CFR text	Certification criterion name	Average cost estimates ($)	
			Average low ($)	Average high ($)
1	§ 170.315(a)(1)	CPOE—medications	0	254,065
2	§ 170.315(a)(2)	CPOE—laboratory	508,1300	1,0162,600
3	§ 170.315(a)(3)	CPOE—diagnostic imaging	0	254,065
4	§ 170.315(a)(4)	DD/DAI Checks for CPOE	5,909,680	11,819,360
5	§ 170.315(a)(5)	Demographics	8,198,400	16,396,800

TABLE 8—TOTAL DEVELOPMENT AND PREPARATION COSTS PER CRITERION FOR HEALTH IT DEVELOPERS—CRITERIA ASSOCIATED WITH THE EHR INCENTIVE PROGRAMS STAGE 3—Continued

["Stage 3 Criteria"]

Item No.	CFR text	Certification criterion name	Average cost estimates ($)	
			Average low ($)	Average high ($)
6	§ 170.315(a)(7)	Problem List	1,567,090	3,134,180
7	§ 170.315(a)(8)	Medication List	0	777,140
8	§ 170.315(a)(9)	Medication Allergy List	0	770,735
9	§ 170.315(a)(10)	Clinical Decision Support	8,608,320	17,216,640
10	§ 170.315(a)(11)	Drug-formulary and Preferred Drug List Checks	4,407,921	8,815,842
11	§ 170.315(a)(12)	Smoking Status	1,626,870	3,253,740
12	§ 170.315(a)(14)	Family Health History	1,317,600	2,635,200
13	§ 170.315(a)(15)	Family Health History—pedigree	732,000	1,756,800
14	§ 170.315(a)(17)	Patient-specific Education Resources	9,120,720	18,241,440
15	§ 170.315(a)(19)	Patient Health Information Capture	2,711,450	5,422,900
16	§ 170.315(a)(20)	Implantable Device List	6,039,000	9,333,000
17	§ 170.315(b)(1)	Transitions of Care	22,966,195	45,932,390
18	§ 170.315(b)(2)	Clinical Information Reconciliation and Incorporation	8,198,400	16,396,800
19	§ 170.315(b)(3)	Electronic Prescribing	14,392,035	28,784,070
20	§ 170.315(b)(6)	Data Portability	1,117,0320	22,340,640
21	§ 170.315(c)(1)	CQMs—record and export	3,006,080	7,515,200
22	§ 170.315(d)(1)	Authentication, Access Control, Authorization	0	1,018,395
23	§ 170.315(d)(2)	Auditable Events and Tamper-resistance	0	830,515
24	§ 170.315(d)(3)	Audit Report(s)	0	854,000
25	§ 170.315(d)(4)	Amendments	0	742,980
26	§ 170.315(d)(5)	Automatic Access Time-out	0	1,018,395
27	§ 170.315(d)(6)	Emergency Access	0	941,535
28	§ 170.315(d)(7)	End-User Device Encryption	0	815,570
29	§ 170.315(d)(8)	Integrity	0	952,210
30	§ 170.315(e)(1)	View, Download, and Transmit to 3rd party	15,628,200	31,256,400
31	§ 170.315(e)(2)	Secure Messaging	0	751,520
32	§ 170.315(f)(1)	Transmission to Immunization Registries	9,146,340	18,292,680
33	§ 170.315(f)(2)	Transmission to Public Health Agencies—syndromic surveillance.	6,251,280	12,502,560
34	§ 170.315(f)(3)	Transmission to Public Health Agencies—reportable laboratory tests and values/results.	1,554,280	3,108,560
35	§ 170.315(f)(4)	Transmission to Cancer Registries	683,200	1,366,400
36	§ 170.315(f)(5)	Transmission to Public Health Agencies—case reporting	640,500	1,281,000
37	§ 170.315(f)(6)	Transmission to Public Health Agencies—antimicrobial use and resistance reporting.	640,500	1,281,000
38	§ 170.315(f)(7)	Transmission to Public Health Agencies—health care surveys	640,500	1,281,000
39	§ 170.315(g)(1)	Automated Numerator Recording	2,766,960	5,533,920
40	§ 170.315(g)(2)	Automated Measure Calculation	9,684,360	19,368,720
41	§ 170.315(g)(3)	Safety-enhanced Design	4867800	9,735,600
42	§ 170.315(g)(4)	Quality Management System	9,803,920	19,607,840
43	§ 170.315(g)(6)	Consolidated CDA Creation Performance	5,904,800	14,762,000
44	§ 170.315(g)(7)	Application Access to Common Clinical Data Set	7,381,000	14,762,000
45	§ 170.315(g)(8)	Accessibility-Centered Design	1,225,490	2,450,980
46	§ 170.315(h)(1)	Direct Project	0	427,000
47	§ 170.315(h)(2)	Direct Project, Edge Protocol, and XDR/XDM	0	213,500

TABLE 9—TOTAL DEVELOPMENT AND PREPARATION COSTS PER CRITERION FOR HEALTH IT DEVELOPERS—CRITERIA NOT ASSOCIATED WITH THE EHR INCENTIVE PROGRAMS STAGE 3

["Stage 3 Criteria"]

Item No.	CFR text	Certification criterion name	Average cost estimates ($)	
			Average low ($)	Average high ($)
1	§ 170.315(a)(6)	Vital Signs, BMI, and Growth Charts	599,264	899,872
2	§ 170.315(a)(13)	Image Results	0	19,520
3	§ 170.315(a)(16)	Patient List Creation	0	19,520
4	§ 170.315(a)(18)	Electronic Medication Administration Record	0	19,520
5	§ 170.315(a)(21)	Social, Psychological, and Behavioral Data	229,360	458,720
6	§ 170.315(a)(22)	Decision Support—knowledge artifact	384,544	769,088
7	§ 170.315(a)(23)	Decision Support—service	223,504	447,008
8	§ 170.315(b)(4)	Incorporate Laboratory Tests and Values/Results	305,488	610,976
9	§ 170.315(b)(5)	Transmission of Laboratory Test Reports	351,360	702,720

TABLE 9—TOTAL DEVELOPMENT AND PREPARATION COSTS PER CRITERION FOR HEALTH IT DEVELOPERS—CRITERIA NOT ASSOCIATED WITH THE EHR INCENTIVE PROGRAMS STAGE 3—Continued

["Stage 3 Criteria"]

Item No.	CFR text	Certification criterion name	Average cost estimates ($)	
			Average low ($)	Average high ($)
10	§ 170.315(b)(7)	Data Segmentation for Privacy—send	439,200	878,400
11	§ 170.315(b)(8)	Data Segmentation for Privacy—receive	439,200	878,400
12	§ 170.315(b)(9)	Care Plan	292,800	488000
13	§ 170.315(c)(2)	CQMs—import and calculate	0	195,200
14	§ 170.315(c)(4)	CQMs—filter	308,416	616,832
15	§ 170.315(d)(9)	Accounting of Disclosures	0	19,520
16	§ 170.315(g)(5)	Accessibility Technology Compatibility	780,800	1,366,400
17	§ 170.315(h)(3)	SOAP Transport and Security Specification and XDR/XDR for Direct Messaging.	0	19,520
18	§ 170.315(h)(4)	Healthcare Provider Directory—query request	117,120	234,240
19	§ 170.315(h)(5)	Healthcare Provider Directory—query response	117,120	234,240
20	§ 170.315(i)(1)	Electronic Submission of Medical Documentation	976,000	1,952,000

ii. Overall Development and Preparation Costs Over a Four-Year Period

We estimate the development and preparation costs over a four-year period because a four-year period aligns with our estimated publication date for a subsequent final rule (Summer 2015) and the year in which CMS proposes that participants in the EHR Incentive Programs *must* use health IT certified to the 2015 Edition (2018) (see the EHR Incentive Programs Stage 3 proposed rule published elsewhere in this issue of the **Federal Register**).

In total, we estimate the overall costs to develop and prepare health IT for certification over a four-year period to be $197.43 million to $407.20 million, with a cost mid-point of approximately $302.32 million. Evenly distributed over calendar years 2015 through 2018, the cost range would be $49.36 million to $101.80 per year with an annual cost mid-point of approximately $75.58. However, we project these costs to be unevenly distributed. We estimate the distribution as follows: 2015 (25%); 2016 (30%); 2017 (30%); and 2018 (15%). We reached this distribution based on these assumptions and information:

- We expect a subsequent 2015 Edition final rule to be published in the summer of 2015 and for health IT developers to spend the rest of the year preparing and developing their health IT to meet the 2015 Edition.
- We expect health IT developers to aggressively work in 2016 and 2017 to prepare and develop their health IT to meet the 2015 Edition as the compliance date for the EHR Incentive Programs CEHRT definition draws near (*i.e.,* 2018) and because health IT certified to the 2015 Edition *could* be used in 2017 under the EHR Incentive Programs Stage 3 proposal for the CEHRT definition.
- We expect health IT developers to continue to prepare and develop health IT to the 2015 Edition in 2018 based on their approach to the 2014 Edition.

Table 10 below represents the costs attributable to this proposed rule distributed as discussed above. The dollar amounts expressed in Table 10 are expressed in 2013 dollars.

TABLE 10—DISTRIBUTED TOTAL DEVELOPMENT AND PREPARATION COSTS FOR HEALTH IT DEVELOPERS (4-YEAR PERIOD)—TOTALS ROUNDED

Year	Ratio (%)	Total low cost estimate ($M)	Total high cost estimate ($M)	Total average cost estimate ($M)
2015	25	49.36	101.80	75.58
2016	30	59.23	122.16	90.70
2017	30	59.23	122.16	90.70
2018	15	29.61	61.08	45.35
4-Year Totals		197.43	407.20	302.32

iii. Testing and Certification Costs for the 2015 Edition

In the RIA of the Permanent Certification Program final rule, we estimated the costs for testing and certification of technologies that would be used for providers to attempt to achieve EHR Incentive Programs Stages 1–3.[267] These costs were based on the requirements of the certification program and a two-year rulemaking cycle for the CEHRT definition and each EHR Incentive Programs stage. We believe the costs we attributed to testing and certification of technologies in support of EHR Incentive Programs Stage 2 in the Permanent Certification Program final rule would encompass the actual testing and certification of technologies to both the 2014 and 2015 Editions. This assessment is based on the number of technologies currently certified to the 2014 Edition and our projections in this proposed rule for the number of technologies that would likely be tested and certified to the 2015 Edition. Further, we note that the estimated costs in the Permanent Certification Program final rule included costs for surveillance of technologies and also estimated the costs for testing and certification above what we understand are the cost ranges

[267] 76 FR 1318

charged by ONC–ACBs today. We welcome comments on our determination and our cost estimates.

b. Benefits

We believe that there will be several significant benefits that may arise from this proposed rule for patients, health care providers, and health IT developers. The 2015 Edition continues to improve health IT interoperability through the adoption of new and updated standards and implementation specifications. For example, many proposed certification criteria include standards and implementation specifications for interoperability that directly support the EHR Incentive Programs, which include objectives and measures for the interoperable exchange of health information and for providing patients electronic access to their health information in structured formats. In addition, proposed certification criteria that support the collection of patient data that could be used to address health disparities would not only benefit patients, but the entire health care delivery system through improved quality of care. The 2015 Edition also supports usability and patient safety through new and enhanced certification requirements for health IT.

Our proposals to make the ONC Health IT Certification Program open and accessible to more types of health IT and for health IT that supports a variety of care and practice settings should benefit health IT developers, providers practicing in other care/practice settings, and consumers through the availability and use of certified health IT that includes capabilities that promote interoperability and enhanced functionality.[268]

We welcome comment on other benefits, including monetary savings, which could be achieved through the proposals we have put forth in this proposed rule.

2. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities.

The Small Business Administration (SBA) establishes the size of small businesses for federal government programs based on average annual receipts or the average employment of a firm. While health IT developers that pursue certification under the ONC Health IT Certification Program represent a small segment of the overall information technology industry, we believe that the entities impacted by this proposed rule most likely fall under the North American Industry Classification System (NAICS) code 541511 ''Custom Computer Programming Services'' specified at 13 CFR 121.201 where the SBA publishes ''Small Business Size Standards by NAICS Industry.'' The SBA size standard associated with this NAICS code is set at $27.5 million in annual receipts[269] which ''indicates the maximum allowed for a concern and its affiliates to be considered small entities.''

Based on our analysis, we believe that there is enough data generally available to establish that between 75% and 90% of entities that are categorized under the NAICS code 541511 are under the SBA size standard, but note that the available data does not show how many of these entities will develop a health IT product that will be certified to the 2015 Edition under the ONC Health IT Certification Program. We also note that with the exception of aggregate business information available through the U.S. Census Bureau and the SBA related to NAICS code 541511, it appears that many health IT developers that pursue certification under the ONC Health IT Certification Program are privately held or owned and do not regularly, if at all, make their specific annual receipts publicly available. As a result, it is difficult to locate empirical data related to many of these health IT developers to correlate to the SBA size standard. However, although not correlated to the size standard for NAICS code 541511, we do have information indicating that over 60% of health IT developers that have had Complete EHRs and/or EHR Modules certified to the 2011 Edition have less than 51 employees.

We estimate that this proposed rule would have effects on health IT developers that are likely to pursue certification under the ONC Health IT Certification Program, some of which may be small entities. However, we believe that we have proposed the minimum amount of requirements necessary to accomplish our policy goals, including a reduction in regulatory burden and additional flexibility for the regulated community, and that no additional appropriate regulatory alternatives could be developed to lessen the compliance burden associated with this proposed rule. We note that this proposed rule does not impose the costs cited in the RIA as compliance costs, but rather as investments which these health IT developers voluntarily take on and expect to recover with an appropriate rate of return. Accordingly, we do not believe that the proposed rule will create a significant impact on a substantial number of small entities, but request comment on whether there are small entities that we have not identified that may be affected in a significant way by this proposed rule. Additionally, the Secretary certifies that this proposed rule will not have a significant impact on a substantial number of small entities.

3. Executive Order 13132—Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Nothing in this proposed rule imposes substantial direct compliance costs on state and local governments, preempts state law or otherwise has federalism implications. We are not aware of any State laws or regulations that are contradicted or impeded by any of the standards, implementation specifications, or certification criteria that we propose for adoption.

4. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. The current inflation-adjusted statutory threshold is approximately $141 million. This proposed rule will not impose an unfunded mandate on State, local, and tribal governments or on the private sector that will reach the threshold level.

OMB reviewed this proposed rule.

List of Subjects in 45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Health care, Health information technology, Health insurance, Health records, Hospitals, Incorporation by

[268] We note that, in general, these benefits will be realized only if health care providers actually adopt new technology. As discussed elsewhere in this RIA, we believe that such adoption—and thus the benefits noted in this section—would be overwhelmingly attributable to CMS's proposed rulemaking.

[269] The SBA references that annual receipts means ''total income'' (or in the case of a sole proprietorship, ''gross income'') plus ''cost of goods sold'' as these terms are defined and reported on Internal Revenue Service tax return forms. *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*

reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

For the reasons set forth in the preamble, 45 CFR subtitle A, subchapter D, part 170, is proposed to be amended as follows:

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

■ 1. The authority citation for part 170 continues to read as follows:

Authority: 42 U.S.C. 300jj–11; 42 U.S.C. 300jj–14; 5 U.S.C. 552.

■ 2. Amend § 170.102 by:

■ a. Removing the ''Base EHR'', ''Certified EHR Technology'', ''Common MU Data Set'', and ''EHR Module'' definitions; and

■ b. Adding in alphanumeric order the definitions for ''2014 Edition Base EHR'', ''2015 Edition Base EHR'', ''2015 Edition health IT certification criteria'', ''Common Clinical Data Set'', ''Device identifier'', ''Global Unique Device Identification Database (GUDID)'', ''Health IT Module'', ''Implantable device'', ''Production identifier'', and ''Unique device identifier''.

The revisions read as follows:

§ 170.102 Definitions.

2014 Edition Base EHR means an electronic record of health-related information on an individual that:

(1) Includes patient demographic and clinical health information, such as medical history and problem lists;

(2) Has the capacity:

(i) To provide clinical decision support;

(ii) To support physician order entry;

(iii) To capture and query information relevant to health care quality;

(iv) To exchange electronic health information with, and integrate such information from other sources;

(v) To protect the confidentiality, integrity, and availability of health information stored and exchanged; and

(3) Has been certified to the certification criteria adopted by the Secretary:

(i) For at least one of the four criteria adopted at § 170.314(a)(1), (18), (19), or (20);

(ii) At § 170.314(a)(3);

(iii) At § 170.314(a)(5) through (8);

(iv) Both § 170.314(b)(1) and (2); or, both § 170.314(b)(8) and (h)(1); or § 170.314(b)(1) and (2) combined with either § 170.314(b)(8) or (h)(1), or both § 170.314(b)(8) and (h)(1);

(v) At § 170.314(b)(7);

(vi) At § 170.314(c)(1) through (3);

(vii) At § 170.314(d)(1) through (8);

(4) Has been certified to the certification criteria at § 170.314(c)(1) and (2):

(i) For no fewer than 9 clinical quality measures covering at least 3 domains from the set selected by CMS for eligible professionals, including at least 6 clinical quality measures from the recommended core set identified by CMS; or

(ii) For no fewer than 16 clinical quality measures covering at least 3 domains from the set selected by CMS for eligible hospitals and critical access hospitals.

* * * * *

2015 Edition Base EHR means an electronic record of health-related information on an individual that:

(1) Includes patient demographic and clinical health information, such as medical history and problem lists;

(2) Has the capacity:

(i) To provide clinical decision support;

(ii) To support physician order entry;

(iii) To capture and query information relevant to health care quality;

(iv) To exchange electronic health information with, and integrate such information from other sources; and

(3) Has been certified to the certification criteria adopted by the Secretary at § 170.315(a)(1), (2), or (3); (a)(5); (a)(7) through (10); (a)(12); (a)(20); (b)(1) and (6); (c)(1); (g)(7) and (h)(1) or (2);

(4) [Reserved]

2015 Edition health IT certification criteria means the certification criteria at § 170.315.

* * * * *

Common Clinical Data Set means the following data expressed, where indicated, according to the specified standard(s):

(1) *Patient name.* For certification to both the 2014 Edition EHR certification criteria and the 2015 Edition health IT certification criteria.

(2) *Sex.* (i) No required standard for certification to the 2014 Edition EHR certification criteria.

(ii) The standard specified in § 170.207(n)(1) for certification to the 2015 Edition health IT certification criteria.

(3) *Date of birth.* For certification to both the 2014 Edition EHR certification criteria and the 2015 Edition health IT certification criteria.

(4) *Race.* (i) The standard specified in § 170.207(f)(1) for certification to the 2014 Edition EHR certification criteria.

(ii) For certification to the 2015 Edition health IT certification criteria:

(A) The standard specified in § 170.207(f)(2);

(B) The standard specified in § 170.207(f)(1) for each race identified in accordance § 170.207(f)(2).

(5) *Ethnicity.* (i) The standard specified in § 170.207(f)(1) for certification to the 2014 Edition EHR certification criteria.

(ii) For certification to the 2015 Edition health IT certification criteria:

(A) The standard specified in § 170.207(f)(2);

(B) The standard specified in § 170.207(f)(1) for each ethnicity identified in accordance § 170.207(f)(2).

(6) *Preferred language.* (i) The standard specified in § 170.207(g)(1) for certification to the 2014 Edition EHR certification criteria.

(ii) The standard specified in § 170.207(g)(2) for certification to the 2015 Edition Health IT certification criteria.

(7) *Smoking status.* For certification to both the 2014 Edition EHR certification criteria and the 2015 Edition health IT certification criteria: The standard specified in § 170.207(h).

(8) *Problems.* (i) At a minimum, the standard specified in § 170.207(a)(3) for certification to the 2014 Edition EHR certification criteria.

(ii) At a minimum, the standard specified in § 170.207(a)(4) for certification to the 2015 Edition Health IT certification criteria.

(9) *Medications.* (i) At a minimum, the standard specified in § 170.207(d)(2) for certification to the 2014 Edition EHR certification criteria.

(ii) At a minimum, the standard specified in § 170.207(d)(3) for certification to the 2015 Edition Health IT certification criteria.

(10) *Medication allergies.* (i) At a minimum, the standard specified in § 170.207(d)(2) for certification to the 2014 Edition EHR certification criteria.

(ii) At a minimum, the standard specified in § 170.207(d)(3) for certification to the 2015 Edition Health IT certification criteria.

(11) *Laboratory test(s).* (i) At a minimum, the standard specified in § 170.207(c)(2) for certification to the 2014 Edition EHR certification criteria.

(ii) At a minimum, the standard specified in § 170.207(c)(3) for certification to the 2015 Edition Health IT certification criteria.

(12) *Laboratory value(s)/result(s).* For certification to both the 2014 Edition EHR certification criteria and the 2015 Edition health IT certification criteria.

(13) *Vital signs.* (i) Height/length, weight, blood pressure, and BMI for

certification to the 2014 Edition EHR certification criteria.

(ii) For certification to the 2015 Edition Health IT certification criteria:

(A) The patient's body height, body weight measured, diastolic blood pressure, systolic blood pressure, heart rate, respiratory rate, body temperature, oxygen saturation in arterial blood by pulse oximetry, body mass index (ratio), and mean blood pressure must be recorded in numerical values only;

(B) In accordance with the standard specified in § 170.207(k)(1) and with the associated applicable unit of measure for the vital sign in the standard specified in § 170.207(m)(1); and including

(*1*) Date and time of vital sign measurement or end time of vital sign measurement;

(*2*) The measuring- or authoring-type source of the vital sign measurement; and

(*3*) *Optional.* Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g).

(14) *Care plan field(s), including goals and instructions.* For certification to the 2014 Edition EHR certification criteria.

(15) Procedures—

(i)(A) At a minimum, the version of the standard specified in § 170.207(a)(3) for certification to the 2014 Edition EHR certification criteria and § 170.207(a)(4) for certification to the 2015 Edition health IT certification criteria, or § 170.207(b)(2); or

(B) For technology primarily developed to record dental procedures, the standard specified in § 170.207(b)(3) for certification to both the 2014 Edition EHR certification criteria and the 2015 Edition health IT certification criteria.

(ii) *Optional.* The standard specified at § 170.207(b)(4) for certification to both the 2014 Edition EHR certification criteria and the 2015 Edition health IT certification criteria.

(16) *Care team member(s).* For certification to both the 2014 Edition EHR certification criteria and the 2015 Edition health IT certification criteria.

(17) *Immunizations.* In accordance with, at a minimum, the standards specified in § 170.207(e)(3) and (4) for certification to the 2015 Edition health IT certification criteria.

(18) *Unique device identifier(s) for a patient's implantable device(s).* For certification to the 2015 Edition health IT certification criteria.

(19) *Assessment and plan of treatment.* For certification to the 2015 Edition health IT certification criteria:

(i) In accordance with the ''Assessment and Plan Section (V2)'' of the standard specified in § 170.205(a)(4); or

(ii) In accordance with the ''Assessment Section (V2)'' and ''Plan of Treatment Section (V2)'' of the standard specified in § 170.205(a)(4).

(20) *Goals.* In accordance with the ''Goals Section'' of the standard specified in § 170.205(a)(4) for certification to the 2015 Edition health IT certification criteria.

(21) *Health concerns.* In accordance with the ''Health Concerns Section'' of the standard specified in § 170.205(a)(4) for certification to the 2015 Edition health IT certification criteria.

* * * * *

Device identifier is defined as it is in 21 CFR 801.3.

* * * * *

Global Unique Device Identification Database (GUDID) is defined as it is in 21 CFR 801.3.

Health IT Module means any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary.

* * * * *

Implantable device is defined as it is in 21 CFR 801.3.

* * * * *

Production identifier is defined as it is in 21 CFR 801.3.

* * * * *

Unique device identifier is defined as it is in 21 CFR 801.3.

§ 170.200 [Amended]

■ 3. In § 170.200, remove the term ''EHR Modules'' and add in its place ''Health IT Modules.''

■ 4. In § 170.202, revise the section heading and add paragraphs (e) and (f) to read as follows:

§ 170.202 Transport standards and other protocols.

* * * * *

(e) *Delivery notification*—(1) *Standard.* ONC Implementation Guide for Delivery Notification in Direct.

(2) [Reserved]

(f) *Provider directories*—(1) *Standard.* Healthcare Provider Directory, Trial Implementation, October 13, 2014.

(2) [Reserved]

■ 5. Amend § 170.204 by—

■ a. Revising paragraphs (a) and (b)(2); and

■ b. Adding paragraphs (b)(3) and (4), (d), and (e).

The additions and revisions read as follows:

§ 170.204 Functional standards.

* * * * *

(a) *Accessibility*—(1) *Standard.* Web Content Accessibility Guidelines (WCAG) 2.0, Level A Conformance (incorporated by reference in § 170.299).

(2) [Reserved]

(b) * * *

(2) *Implementation specifications.* HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Draft Standard for Trial Use, Release 1.

(3) *Standard.* HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. (''Infobutton''), Knowledge Request, Release 2. *Implementation specifications.* HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1.

(4) *Standard.* HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application (''Infobutton''), Knowledge Request, Release 2. *Implementation specifications.* HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4.

* * * * *

(d) *Clinical decision support knowledge artifacts*—(1) *Standard.* HL7 Version 3 Standard: Clinical Decision Support Knowledge Artifact Specification, Release 1.2, Draft Standard for Trial Use.

(2) [Reserved]

(e) *Clinical decision support service.* (1) HL7 Implementation Guide: Decision Support Service, Release 1.1, US Realm, Draft Standard for Trial Use.

(2) [Reserved]

■ 6. Amend § 170.205 by—

■ a. Adding paragraphs (a)(4) and (5), (d)(4), and (e)(4);

■ b. Revising paragraphs (g), (i), and (j); and

■ c. Adding paragraphs (l), (m), (n), (o), (p), (q), (r), and (s).

The additions and revisions read as follows:

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

* * * * *

(a) * * *

(4) *Standard.* HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.0.

(5) *Implementation specifications.* (i) HL7 Implementation Guide for CDA® Release 2: Additional CDA R2 Templates—Clinical Documents for Payers—Set 1, Release 1—US Realm.

(ii) HL7 Implementation Guide for CDA Release 2: Digital Signatures and Delegation of Rights, Release 1.

(iii) Author of Record Level 1: Implementation Guide.

(iv) Provider Profiles Authentication: Registration Implementation Guide.

* * * * *

(d) * * *

(4) *Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent, Ambulatory Care, and Inpatient Settings, Release 2.0.

(e) * * *

(4) *Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5.

* * * * *

(g) *Electronic transmission of lab results to public health agencies*—(1) *Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (incorporated by reference in § 170.299) with Errata and Clarifications, (incorporated by reference in § 170.299) and ELR 2.5.1 Clarification Document for EHR Technology Certification (incorporated by reference in § 170.299).

(2) *Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm), Draft Standard for Trial Use, Release 1.1.

* * * * *

(i) *Cancer information*—(1) *Standard.* HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition (incorporated by reference in § 170.299). *Implementation specifications.* Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA), Release 1.0 (incorporated by reference in § 170.299).

(2) *Standard.* HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition (incorporated by reference in § 170.299). *Implementation specifications.* HL7 Implementation Guide for CDA © Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1.

(j) *Electronic incorporation and transmission of lab results*—(1) *Standard.* HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface (incorporated by reference in § 170.299).

(2) *Standard.* HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Draft Standard for Trial Use, Release 2—US Realm (S&I Framework LRI).

* * * * *

(l) *Laboratory orders*—(1) *Standard.* HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Draft Standard for Trial Use, Release 2—US Realm.

(2) *Standard.* HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2, Version 1.2.

(m) *Family health history.* (1) HL7 Version 3 Standard: Clinical Genomics; Pedigree (incorporated by reference in § 170.299). *Implementation specifications.* HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability.

(2) [Reserved]

(n) *Drug formulary checking*—(1) *Standard.* The standard specified at 42 CFR 423.160(b)(5)(iii).

(2) [Reserved]

(o) *Data segmentation for privacy*—(1) *Standard.* HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1.

(2) [Reserved]

(p) *XDM package processing*—(1) *Standard.* IHE IT Infrastructure Technical Framework Volume 2b (ITI TF–2b).

(2) [Reserved]

(q) *Public health—case reporting information*—(1) *Standard.* IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation.

(2) [Reserved]

(r) *Public health—antimicrobial use and resistance information*—(1) *Standard.* The following sections of HL7 Implementation Guide for CDA® Release 2—Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm. Technology is only required to conform to the following sections of the implementation guide:

(i) HAI Antimicrobial Use and Resistance (AUR) Antimicrobial Resistance Option (ARO) Report (Numerator) specific document template in Section 2.1.2.1 (pages 69–72);

(ii) Antimicrobial Resistance Option (ARO) Summary Report (Denominator) specific document template in Section 2.1.1.1 (pages 54–56); and

(iii) Antimicrobial Use (AUP) Summary Report (Numerator and Denominator) specific document template in Section 2.1.1.2 (pages 56–58).

(2) [Reserved]

(s) *Public health—health care survey information*—(1) *Standard.* HL7 Implementation Guide for CDA Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, Draft Standard for Trial Use.

(2) [Reserved]

■ 7. Amend § 170.207 by—

■ a. Adding paragraphs (a)(4), (c)(3), (d)(3), (e)(3) and (4);

■ b. Revising paragraphs (f) and (g); and

■ c. Adding paragraph (k), reserved paragraph (l), and paragraphs (m), (n), and (o).

The additions and revisions read as follows:

§ 170.207 Vocabulary standards for representing electronic health information.

* * * * *

(a) * * *

(4) *Standard.* IHTSDO SNOMED CT®, U.S. Edition, September 2014 Release.

* * * * *

(c) * * *

(3) *Standard.* Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.50, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.

(d) * * *

(3) *Standard.* RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, February 2, 2014 Release.

(e) * * *

(3) *Standard.* HL7 Standard Code Set CVX—Vaccines Administered, updates through February 2, 2015.

(4) *Standard.* National Drug Code Directory—Vaccine Codes, updates through January 15, 2015.

(f) *Race and Ethnicity*—(1) *Standard.* The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997.

(2) *Standard.* ''Race & Ethnicity—CDC'' code system in the PHIN Vocabulary Access and Distribution System (VADS), Release 3.3.9.

(g) *Preferred language*—(1) *Standard.* As specified by the Library of Congress, ISO 639–2 alpha-3 codes limited to those that also have a corresponding alpha-2 code in ISO 639–1 (incorporated by reference in § 170.299).

(2) *Standard.* Request for Comments (RFC) 5646.

* * * * *

(k) *Vital signs*—(1) *Standard.* Vital signs must be identified, at a minimum, with the version of LOINC® codes adopted at paragraph (c)(3) of this section attributed as follows:

(i) *Systolic blood pressure.* 8480–6

(ii) *Diastolic blood pressure.* 8462–4

(iii) *Body height.* 8302–2

(iv) *Body weight measured.* 3141–9

(v) *Heart rate.* 8867–4
(vi) *Respiratory rate.* 9279–1
(vii) *Body temperature.* 8310–5
(viii) O*xygen saturation in arterial blood by pulse oximetry.* 59408–5
(ix) *Body mass index (BMI) [ratio].* 39156–5
(x) *Mean blood pressure.* 8478–0
(2) [Reserved]
(l) [Reserved]
(m) *Numerical references*—(1) *Standard.* The Unified Code of Units of Measure, Revision 1.9.
(2) [Reserved]
(n) *Sex*—(1) *Standard.* Birth sex must be coded in accordance with HL7 Version 3 attributed as follows:
(i) *Male.* M
(ii) *Female.* F
(iii) *Unknown.* UNK
(2) [Reserved]
(o) *Social, psychological, and behavioral data*—(1) *Standard.* Sexual orientation must be coded in accordance with, at a minimum, the version of SNOMED CT® codes adopted at paragraph (a)(4) of this section for paragraphs (o)(1)(i) through (iii) of this section and HL7 Version 3 for paragraphs (o)(1)(iv) through (vi) of this section, attributed as follows:
(i) *Homosexual.* 38628009
(ii) *Heterosexual.* 20430005
(iii) *Bisexual.* 42035005
(iv) *Other.* nullFlavor OTH
(v) *Asked but unknown.* nullFlavor ASKU
(vi) *Unknown.* nullFlavor UNK
(2) *Standard.* Gender identity must be coded in accordance with, at a minimum, the version of SNOMED CT® codes adopted at paragraph (a)(4) of this section for paragraphs (o)(2)(i) through (v) of this section and HL7 Version 3 for paragraphs (o)(2)(vi) and (vii) of this section, attributed as follows:
(i*) Identifies as male gender.* 446151000124109
(ii) *Identifies as female gender.* 446141000124107
(iii) *Female-to-male transsexual.* 407377005
(iv) *Male-to-female transsexual.* 407376001
(v) *Identifies as non-conforming gender.* 446131000124102
(vi) *Other.* nullFlavor OTH
(vii) *Asked but unknown.* nullFlavor ASKU
(3) *Financial resource strain.* Financial resource strain must be coded in accordance with, at a minimum, the version of LOINC® codes adopted at paragraph (c)(3) of this section and attributed with the LOINC® code and LOINC® answer list ID.
(4) *Education.* Education must be coded in accordance with, at a minimum, the version of LOINC® codes adopted at paragraph (c)(3) of this section and attributed with LOINC® code 63504–5 and LOINC® answer list ID LL1069–5.
(5) *Stress.* Stress must be coded in accordance with, at a minimum, the version of LOINC® codes adopted at paragraph (c)(3) of this section and attributed with the LOINC® code and LOINC® answer list ID.
(6) *Depression.* Depression must be coded in accordance with, at a minimum, the version of LOINC® codes adopted at paragraph (c)(3) of this section and attributed with LOINC® codes 55757–9, 44250–9 (with LOINC® answer list ID LL358–3), 44255–8 (with LOINC® answer list ID LL358–3), and 55758–7 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)).
(7) *Physical activity.* Physical activity must be coded in accordance with, at a minimum, the version of LOINC® codes adopted at paragraph (c)(3) of this section and attributed with LOINC® codes 68515–6 and 68516–4. The answers must be coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(1).
(8) *Alcohol use.* Alcohol use must be coded in accordance with, at a minimum, the version of LOINC® codes adopted at paragraph (c)(3) of this section and attributed with LOINC® codes 72109–2, 68518–0 (with LOINC® answer list ID LL2179–1), 68519–8 (with LOINC® answer list ID LL2180–9), 68520–6 (LOINC® answer list ID LL2181–7), and 75626–2.
(9) *Social connection and isolation.* Social connection and isolation must be coded in accordance with, at a minimum, the version of LOINC® codes adopted at paragraph (c)(3) of this section and attributed with the LOINC® code and LOINC® answer list ID.
(10) *Exposure to violence (intimate partner violence).* Exposure to violence: intimate partner violence must be coded in accordance with, at a minimum, the version of LOINC® codes adopted at paragraph (c)(3) of this section and attributed with the LOINC® code and LOINC® answer list ID.

■ 8. In § 170.210:
■ a. Amend paragraphs (e)(1)(i) and (e)(3) by removing the term ''EHR technology'' and adding in its place ''health IT''; and
■ b. Add paragraph (a)(3).
The addition reads as follows:

§ 170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.

* * * * *

(a) * * *
(3) *General.* Any encryption algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140–2, October 8, 2014.

* * * * *

■ 9. In § 170.300, revise paragraph (d) to read as follows:

§ 170.300 Applicability.

* * * * *

(d) In §§ 170.314 and 170.315, all certification criteria and all capabilities specified within a certification criterion have general applicability (*i.e.,* apply to any health care setting) unless designated as ''inpatient setting only'' or ''ambulatory setting only.''
(1) *Inpatient setting only* means that the criterion or capability within the criterion is only required for certification of technology designed for use in an inpatient setting.
(2) *Ambulatory setting only* means that the criterion or capability within the criterion is only required for certification of technology designed for use in an ambulatory setting.

§ 170.314 [Amended]

■ 10. In § 170.314:
■ a. In paragraph (a)(3)(i)(A), remove ''§ 170.207(f)'' and add in its place ''§ 170.207(f)(1)'';
■ b. In paragraph (a)(3)(i)(B), remove ''§ 170.207(g)'' and add in its place ''§ 170.207(g)(1)'';
■ c. In paragraph (a)(8)(iii)(B)(*2*), remove ''paragraph (b)(1)(iii)'' and add in its place ''paragraph (b)(1)(iii)(B) or (b)(9)(ii)(D)'';
■ d. In paragraphs (b)(2)(i) introductory test, (b)(7) introductory text, (b)(8)(iii) introductory text, (e)(1)(i)(A)(*1*), and (e)(2)(iii)(A), remove the term ''Common MU Data Set'' and add in its place ''Common Clinical Data Set'';
■ e. In paragraph (b)(5)(i)(A)(*1*), remove ''§ 170.205(j)'' and add in its place ''§ 170.205(j)(1)'';
■ f. In paragraph (b)(6), remove ''§ 170.205(j)'' and add in its place ''§ 170.205(j)(1)'';
■ g. In paragraph (e)(1)(i)(A) introductory text, remove ''§ 170.204(a)'' and add in its place ''§ 170.204(a)(1)'';
■ h. In paragraph (f)(4)(i), remove ''§ 170.205(g)'' and add in its place ''§ 170.205(g)(1)''; and
■ i. In paragraph (f)(6)(i), remove ''§ 170.205(i)'' and add in its place '' § 170.205(i)(1)''.
■ 11. Add § 170.315 to read as follows:

§ 170.315 2015 Edition health IT certification criteria.

The Secretary adopts the following certification criteria for health IT. Health IT must be able to electronically perform the following capabilities in accordance with all applicable standards and implementation specifications adopted in this part:

(a) *Clinical*—(1) *Computerized provider order entry—medications.* Technology must enable a user to record, change, and access medication orders.

(2) *Computerized provider order entry—laboratory.* (i) Technology must enable a user to record, change, and access laboratory orders.

(ii) Technology must be able to receive and incorporate a new or updated laboratory order compendium in accordance with the standard specified in § 170.205(l)(2) and, at a minimum, the version of the standard in § 170.207(c)(3).

(iii) *Ambulatory setting only.* Technology must enable a user to create laboratory orders for electronic transmission in accordance with the standard specified in § 170.205(l)(1) and, at a minimum, the version of the standard in § 170.207(c)(3).

(3) *Computerized provider order entry—diagnostic imaging.* Technology must enable a user to record, change, and access diagnostic imaging orders.

(4) *Drug-drug, drug-allergy interaction checks for CPOE*—(i) *Interventions.* Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list.

(ii) *Adjustments.* (A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.

(B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.

(iii) *Interaction check response documentation.* (A) Technology must be able to record at least one action taken and by whom in response to drug-drug or drug-allergy interaction checks.

(B) Technology must be able to generate either a human readable display or human readable report of actions taken and by whom in response to drug-drug or drug-allergy interaction checks.

(5) *Demographics.* (i) Enable a user to record, change, and access patient demographic data including preferred language, sex, race, ethnicity, and date of birth.

(A) *Race and ethnicity.* (*1*) Enable each one of a patient's races to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify race.

(*2*) Enable each one of a patient's ethnicities to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify ethnicity.

(*3*) Aggregate each one of the patient's races and ethnicities recorded in accordance with paragraphs (a)(5)(i)(A)(*1*) and (*2*) of this section to the categories in the standard specified in § 170.207(f)(1).

(B) Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g)(2) and whether a patient declines to specify a preferred language.

(C) Enable sex to be recorded in accordance with the standard specified in § 170.207(n)(1).

(ii) *Inpatient setting only.* Enable a user to record, change, and access the preliminary cause of death and date of death in the event of mortality.

(6) *Vital signs, body mass index, and growth charts*—(i) *Vital signs.* Enable a user to record, change, and access, at a minimum, a patient's height, weight, diastolic blood pressure, systolic blood pressure, heart rate, respiratory rate, temperature, oxygen saturation in arterial blood by pulse oximetry, body mass index [ratio], and mean blood pressure in accordance with the following (The patient's height/length, weight, diastolic blood pressure, systolic blood pressure, heart rate, respiratory rate, temperature, oxygen saturation in arterial blood by pulse oximetry, body mass index [ratio], and mean blood pressure must be recorded in numerical values only.):

(A) The standard specified in § 170.207(k)(1) and with the associated applicable unit of measure for the vital sign in the standard specified in § 170.207(m)(1);

(B) *Metadata.* For each vital sign in paragraph (a)(6)(i) of this section, the technology must also record the following:

(*1*) Date and time of vital sign measurement or end time of vital sign measurement;

(*2*) The measuring- or authoring-type source of the vital sign measurement; and

(*3*) *Optional.* Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g); and

(C) *Metadata for* oxygen saturation in arterial blood by pulse oximetry. For the oxygen saturation in arterial blood by pulse oximetry, the technology must enable a user to record, change, and access the patient's inhaled oxygen concentration identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with LOINC® code 8478–0.

(ii) *Optional—Body mass index percentile per age and sex.* Enable a user to record, change, and access a patient's body mass index [percentile] per age and sex for patients two to twenty years of age in accordance with the following (The patient's body mass index [percentile] per age and sex must be recorded in numerical values only.):

(A) Identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with LOINC® code 59576–9 and with the associated applicable unit of measure in the standard specified in § 170.207(m)(1); and

(B) *Metadata.* The technology must also record the following:

(*1*) Date and time of vital sign measurement or end time of vital sign measurement;

(*2*) The measuring- or authoring-type source of the vital sign measurement;

(*3*) The patient's date of birth;

(*4*) The patient's sex in accordance with the standard specified in § 170.207(n)(1); and

(*5*) *Optional.* Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g).

(iii) *Optional—Weight for length per age and sex.* Enable a user to record, change, and access a patient's weight for length per age and sex for patients less than three years of age in accordance with the following (The patient's weight for length per age and sex must be recorded in numerical values only.):

(A) Identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with the LOINC® code and with the associated applicable unit of measure in the standard specified in § 170.207(m)(1); and

(B) *Metadata.* The technology must record the following:

(*1*) Date and time of vital sign measurement or end time of vital sign measurement;

(*2*) The measuring- or authoring-type source of the vital sign measurement;

(*3*) The patient's date of birth;

(*4*) The patient's sex in accordance with the standard specified in § 170.207(n)(1); and

(*5*) *Optional.* Date and time of vital sign measurement or end time of vital

sign measurement in accordance with the standard in § 170.210(g).

(iv) *Optional—Head occipital-frontal circumference.* Enable a user to record, change, and access a patient's head occipital-frontal circumference for patients less than three years of age in accordance with the following (The patient's head occipital-frontal circumference must be recorded in numerical values only.):

(A) Identified, at a minimum, with the version of the standard adopt in § 170.207(c)(3) and attributed with LOINC® code 8287–5 and with the associated applicable unit of measure in the standard specified in § 170.207(m)(1); and

(B) *Metadata.* The technology must also record the following:

(*1*) Date and time of vital sign measurement or end time of vital sign measurement;

(*2*) The measuring- or authoring-type source of the vital sign measurement;

(*3*) The patient's date of birth;

(*4*) The patient's age in accordance with the standard specified in § 170.207(n)(1); and

(*5*) *Optional.* Date and time of vital sign measurement or end time of vital sign measurement in accordance with the standard in § 170.210(g).

(v) *Optional—Calculate body mass index.* Automatically calculate and display body mass index based on a patient's height and weight.

(vi) *Optional—Plot and display growth charts.* Plot and display, upon request, growth charts for patients.

(7) *Problem list.* Enable a user to record, change, and access a patient's active problem list:

(i) *Ambulatory setting.* Over multiple encounters in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4); or

(ii) *Inpatient setting.* For the duration of an entire hospitalization in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4).

(8) *Medication list.* Enable a user to record, change, and access a patient's active medication list as well as medication history:

(i) *Ambulatory setting.* Over multiple encounters; or

(ii) *Inpatient setting.* For the duration of an entire hospitalization.

(9) *Medication allergy list.* Enable a user to record, change, and access a patient's active medication allergy list as well as medication allergy history:

(i) *Ambulatory setting.* Over multiple encounters; or

(ii) *Inpatient setting.* For the duration of an entire hospitalization.

(10) *Clinical decision support*—(i) *Evidence-based decision support interventions.* Enable a limited set of identified users to select (*i.e.,* activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data:

(A) Problem list;

(B) Medication list;

(C) Medication allergy list;

(D) At least one demographic specified in paragraph (a)(5)(i) of this section;

(E) Laboratory tests; and

(F) Vital signs.

(ii) *Linked referential clinical decision support.* (A) Technology must be able to identify for a user diagnostic and therapeutic reference information in accordance with the standard and implementation specifications at § 170.204(b)(3) or (4).

(B) For paragraph (a)(10)(ii)(A) of this section, technology must be able to identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (a)(10)(i)(A), (B), and (D) of this section.

(iii) *Clinical decision support configuration.* (A) Enable interventions and reference resources specified in paragraphs (a)(10)(i) and (ii) of this section to be configured by a limited set of identified users (*e.g.,* system administrator) based on a user's role.

(B) Technology must enable interventions to be:

(*1*) Based on the data referenced in paragraphs (a)(10)(i)(A) through (F) of this section.

(*2*) When a patient's medications, medication allergies, problems, and laboratory tests and values/results are incorporated from a transition of care/referral summary received and pursuant to paragraph (b)(2)(iii)(D) of this section.

(*3*) *Ambulatory setting only.* When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(4) of this section.

(iv) *CDS intervention interaction.* Interventions provided to a user in paragraphs (a)(10)(i) through (iii) of this section must occur when a user is interacting with technology.

(v) *Source attributes.* Enable a user to review the attributes as indicated for all clinical decision support resources:

(A) For evidence-based decision support interventions under paragraph (a)(10)(i) of this section:

(*1*) Bibliographic citation of the intervention (clinical research/guideline);

(*2*) Developer of the intervention (translation from clinical research/guideline);

(*3*) Funding source of the intervention development technical implementation; and

(*4*) Release and, if applicable, revision date(s) of the intervention or reference source.

(B) For linked referential clinical decision support in paragraph (a)(10)(ii) of this section and drug-drug, drug-allergy interaction checks in paragraph (a)(4) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).

(vi) *Intervention response documentation.* (A) Technology must be able to record at least one action taken and by whom in response to clinical decision support interventions.

(B) Technology must be able to generate either a human readable display or human readable report of actions taken and by whom in response to clinical decision support interventions.

(11) *Drug-formulary and preferred drug list checks.* Technology must either meet paragraph (a)(11)(i) or (ii) of this section.

(i) *Drug formulary checks.* (A) Automatically check whether a drug formulary exists for a given patient and medication.

(B) Indicate for a user the last update of the drug formulary; and

(C) Receive and incorporate a formulary and benefit file in accordance with the standard specified in § 170.205(n)(1).

(ii) *Preferred drug list checks.* (A) Automatically check whether a preferred drug list exists for a given patient and medication.

(B) Indicate for a user the last update of the preferred drug list.

(12) *Smoking status.* Enable a user to record, change, and access the smoking status of a patient in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4).

(13) *Image results.* Indicate to a user the availability of a patient's images and narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable electronic access to such images and narrative interpretations.

(14) *Family health history.* Enable a user to record, change, and access a patient's family health history in accordance with the familial concepts or expressions included in, at a minimum, the version of the standard in § 170.207(a)(4).

(15) *Family health history—pedigree.* Technology must be able to create and incorporate a patient's family health history in accordance with the standard

and implementation specification specified in § 170.205(m)(1).

(16) *Patient list creation.* Enable a user to dynamically select, sort, access, and create patient lists by: date and time; and based on each one and at least one combination of the following data:

(i) Problems;

(ii) Medications;

(iii) Medication allergies;

(iv) At least one demographic specified in paragraph (a)(5)(i) of this section;

(v) Laboratory tests and values/results; and

(vi) *Ambulatory setting only.* Patient communication preferences.

(17) *Patient-specific education resources.* Technology must be able to:

(i) Identify patient-specific education resources based on data included in the patient's problem list and medication list in accordance with the standard (and implementation specifications) specified in § 170.204(b)(3) or (4); and

(ii) Request that patient-specific education resources be identified in accordance with the standard in § 170.207(g)(2).

(18) *Electronic medication administration record.* (i) In combination with an assistive technology that provides automated information on the ''rights'' specified in paragraphs (a)(18)(i)(A) through (E) of this section, enable a user to verify the following before administering medication(s):

(A) *Right patient.* The patient to whom the medication is to be administered matches the medication to be administered.

(B) *Right medication.* The medication to be administered matches the medication ordered for the patient.

(C) *Right dose.* The dose of the medication to be administered matches the dose of the medication ordered for the patient.

(D) *Right route.* The route of medication delivery matches the route specified in the medication order.

(E) *Right time.* The time that the medication was ordered to be administered compared to the current time.

(ii) *Right documentation.* Record the time and date in accordance with the standard specified in § 170.210(g), and user identification when a medication is administered.

(19) *Patient health information capture.* Technology must be able to enable a user to:

(i) Identify, record, and access patient health information documents;

(ii) Reference and link to patient health information documents; and

(iii) Record and access information directly shared by a patient.

(20) *Implantable device list.* (i) Enable a user to record, change, and access, a list of Unique Device Identifiers associated with a patient's Implantable Device(s).

(ii) Parse the following data elements from a Unique Device Identifier:

(A) Device Identifier;

(B) Batch/lot number;

(C) Expiration date;

(D) Production date; and

(E) Serial number.

(iii) Retrieve the ''Device Description'' attribute associated with a Unique Device Identifier in the Global Unique Device Identification Database.

(iv) For each Unique Device Identifier in a patient's list of implantable devices, enable a user to access the following:

(A) The parsed data elements specified under paragraph (a)(20)(ii) of this section that are associated with the UDI; and

(B) The retrieved data element specified under paragraph (a)(20)(iii) of this section.

(21) *Social, psychological, and behavioral data.* Enable a user to record, change, and access, at a minimum, one of the following patient social, psychological, and behavioral data.

(i) *Sexual orientation.* Enable sexual orientation to be recorded in accordance with the standard specified in § 170.207(o)(1) and whether a patient declines to specify sexual orientation.

(ii) *Gender identity.* Enable gender identity to be recorded in accordance with the standard specified in § 170.207(o)(2) and whether a patient declines to specify gender identity.

(iii) *Financial resource strain.* Enable financial resource strain to be recorded in accordance with the standard specified in § 170.207(o)(3) and whether a patient declines to specify financial resource strain.

(iv) *Education.* Enable education to be recorded in accordance with the standard specified in § 170.207(o)(4) and whether a patient declines to specify education.

(v) *Stress.* Enable stress to be recorded in accordance with the standard specified in § 170.207(o)(5) and whether a patient declines to specify stress.

(vi) *Depression.* Enable depression to be recorded in accordance with the standard specified in § 170.207(o)(6) and whether a patient declines to specify stress.

(vii) *Physical activity.* Enable physical activity to be recorded in accordance with the standard specified in § 170.207(o)(7) and whether a patient declines to specify physical activity.

(viii) *Alcohol use.* Enable alcohol use to be recorded in accordance with the standard specified in § 170.207(o)(8) and whether a patient declines to specify alcohol use.

(ix) *Social connection and isolation.* Enable social connection and isolation to be recorded in accordance the standard specified in § 170.207(o)(9) and whether a patient declines to specify social connection and isolation.

(x) *Exposure to violence (intimate partner violence).* Enable exposure to violence (intimate partner violence) to be recorded in accordance with the standard specified in § 170.207(o)(10) and whether a patient declines to specify exposure to violence (intimate partner violence).

(22) *Decision support—knowledge artifact.* Enable a user to send and receive clinical decision support knowledge artifacts in accordance with the standard specified in § 170.204(d)(1).

(23) *Decision support—service.* Enable a user to send and receive electronic clinical guidance in accordance with the standard specified in § 170.204(e)(1).

(b) *Care coordination*—(1) *Transitions of care*—(i) *Send and receive via edge protocol.* Technology must be able to:

(A) Send transitions of care/referral summaries through a method that conforms to the standard specified in § 170.202(d); and

(B) Receive transitions of care/referral summaries through a method that conforms to the standard specified in § 170.202(d) from a service that has implemented the standard specified in § 170.202(a).

(C) *XDM processing.* Receive and make available the contents of a XDM package formatted in accordance with the standard adopted in § 170.205(p)(1) if the technology is also being certified using an SMTP-based edge protocol.

(ii) *Validate and display*—(A) *Validate C–CDA conformance—system performance.* Technology must demonstrate its ability to detect valid and invalid transition of care/referral summaries received and formatted in accordance with both of the standards specified in § 170.205(a)(3) and

(4). This includes the ability to:

(*1*) Parse each of the document types formatted according to the following document templates: CCD; Consultation Note; History and Physical; Progress Note; Care Plan; Transfer Summary; Referral Note, and Discharge Summary.

(*2*) Detect errors in corresponding ''document-templates,'' ''section-templates,'' and ''entry-templates,'' including invalid vocabulary standards and codes not specified in either of the standards adopted in § 170.205(a)(3) and (4);

(*3*) Identify valid document-templates and process the data elements required

in the corresponding section-templates and entry-templates from either of the standards adopted in § 170.205(a)(3) and (4);

(*4*) Correctly interpret empty sections and null combinations; and

(*5*) Record errors encountered and allow for a user to be notified of or review the errors produced.

(B) Technology must be able to display in human readable format the data included in transition of care/referral summaries received and formatted according to the standards specified in § 170.205(a)(3) and (4).

(C) *Section views.* Allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary received and formatted in accordance with either of the standards adopted in § 170.205(a)(3) and (4).

(iii) *Create.* (A) Enable a user to create a transition of care/referral summary:

(*1*) Formatted according to the standards adopted in § 170.205(a)(3);

(*2*) Formatted according to the standards adopted in § 170.205(a)(4); and

(*3*) Includes, at a minimum, the Common Clinical Data Set and the following data expressed, where applicable, according to the specified standard(s):

(*i*) *Encounter diagnoses.* The standard specified in § 170.207(i) or, at a minimum, the version of the standard specified in § 170.207(a)(4);

(*ii*) Cognitive status;

(*iii*) Functional status;

(*iv*) *Ambulatory setting only.* The reason for referral; and referring or transitioning provider's name and office contact information; and

(*v*) *Inpatient setting only.* Discharge instructions.

(B) *Patient matching data quality.* Technology must be capable of creating a transition of care/referral summary that includes the following data and, where applicable, represent such data according to the additional constraints specified below:

(*1*) *Data.* first name, last name, maiden name, middle name (including middle initial), suffix, date of birth, place of birth, current address, historical address, phone number, and sex.

(*2*) *Constraint.* Represent last/family name according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0.

(*3*) *Constraint.* Represent suffix according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0 (JR, SR, I, II, III, IV, V, RN, MD, Ph.D., ESQ). If no suffix exists, the field should be entered as null.

(*4*) *Constraint.* Represent the year, month and date of birth are required fields while hour, minute and second should be optional fields. If hour, minute and second are provided then either time zone offset should be included unless place of birth (city, region, country) is provided; in latter local time is assumed. If date of birth is unknown, the field should be marked as null.

(*5*) *Constraint.* Represent phone number (home, business, cell) in the ITU format specified in ITU–T E.123 and ITU–T E.164. If multiple phone numbers are present, all should be included.

(*6*) *Constraint.* Represent sex in accordance with the standard adopted at § 170.207(n)(1).

(2) *Clinical information reconciliation and incorporation*—(i) *General requirements.* Paragraphs (b)(2)(ii) and (iii) of this section must be completed based on the receipt of a transition of care/referral summary formatted in accordance with the standard adopted in § 170.205(a)(3) as well as separately to the standard adopted in § 170.205(a)(4) using the Continuity of Care Document, Discharge Summary Document and Referral Summary document templates.

(ii) *Correct patient.* Upon receipt of a transition of care/referral summary formatted according to either of the standards adopted at § 170.205(a)(3) or (4), technology must be able to demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient.

(iii) *Reconciliation.* Enable a user to reconcile the data that represent a patient's active medication list, medication allergy list, and problem list as follows. For each list type:

(A) Simultaneously display (*i.e.,* in a single view) the data from at least two sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date;

(B) Enable a user to create a single reconciled list of medications, medication allergies, or problems;

(C) Enable a user to review and validate the accuracy of a final set of data; and

(D) Upon a user's confirmation, automatically update the list, and incorporate the following data expressed according to the specified standard(s):

(*1*) *Medications.* At a minimum, the version of the standard specified in § 170.207(d)(3);

(*2*) *Medication allergies.* At a minimum, the version of the standard specified in § 170.207(d)(3); and

(*3*) *Problems.* At a minimum, the version of the standard specified in § 170.207(a)(4).

(iv) *System verification.* Based on the data reconciled and incorporated, the technology must be able to create a file formatted according to the standard adopted at § 170.205(a)(4) using the Continuity of Care Document document template.

(3) *Electronic prescribing.* (i) Enable a user to prescribe, send, and respond to prescription-related transactions for electronic transmission in accordance with the standard specified at § 170.205(b)(2), and, at a minimum, the version of the standard specified in § 170.207(d)(3), as follows:

(A) Create new prescriptions (NEWRX);

(B) Change prescriptions (RXCHG, CHGRES);

(C) Cancel prescriptions (CANRX, CANRES);

(D) Refill prescriptions (REFREQ, REFRES);

(E) Receive fill status notifications (RXFILL); and

(F) Request and receive medication history information (RXHREQ, RXHRES).

(ii) Enable a user to enter, receive, and transmit structured and codified prescribing instructions for the transactions listed in paragraph (b)(3)(i) of this section for electronic transmission in accordance with the standard specified at § 170.205(b)(2) and, at a minimum, for at least the following component composites:

(A) Repeating Sig;

(B) Code System;

(C) Sig Free Text String;

(D) Dose;

(E) Dose Calculation;

(F) Vehicle;

(G) Route of Administration;

(H) Site of Administration;

(I) Sig Timing;

(J) Duration;

(K) Maximum Dose Restriction;

(L) Indication; and

(M) Stop.

(iii) Technology must limit a user's ability to prescribe all medications in only the metric standard.

(iv) Technology must always insert leading zeroes before the decimal point for amounts less than one and must not allow trailing zeroes after a decimal point when a user prescribes medications.

(4) *Incorporate laboratory tests and values/results*—(i) *Receive results*—(A) *Ambulatory setting only.* (*1*) Receive and incorporate clinical laboratory tests and

values/results in accordance with the standard specified in § 170.205(j)(2); and, at a minimum, the version of the standard specified in § 170.207(c)(3).

(*2*) Display the tests and values/results received in human readable format.

(B) *Inpatient setting only.* Receive clinical laboratory tests and values/results in a structured format and display such tests and values/results in human readable format.

(ii) Display the test report information:

(A) Specified in 42 CFR 493.1291(a)(1) through (3) and (c)(1) through (7);

(B) Related to reference intervals or normal values as specified in 42 CFR 493.1291(d);

(C) For alerts and delays as specified in 42 CFR 493.1291(g) and (h); and

(D) For corrected reports as specified in 42 CFR 493.1291(k)(2).

(iii) Attribute, associate, or link a laboratory test and value/result with a laboratory order or patient record.

(5) *Transmission of laboratory test reports.* Technology must be able to electronically create laboratory test reports for electronic transmission in accordance with the standard specified in § 170.205(j)(2) and, at a minimum, the version of the standard specified in § 170.207(c)(3).

(6) *Data portability*—(i) *General requirements for export summary configuration.* A user must be able to set the following configuration options when using technology to create an export summary or set of export summaries for patients whose information is stored in the technology. A user must be able to execute these capabilities at any time the user chooses and without subsequent developer assistance to operate.

(ii) *Document creation configuration*—(A) *Document-template types.* A user must be able to configure the technology to create an export summary or export summaries formatted according to the standard adopted at § 170.205(a)(4) for any of the following document-template types.

(*1*) *Generally applicable.* CCD; Consultation Note; History and Physical; Progress Note; Care Plan; Transfer Summary; and Referral Note.

(*2*) *Inpatient setting only.* Discharge Summary.

(B) For any document-template selected the technology must be able to include, at a minimum, the Common Clinical Data Set and the following data expressed, where applicable, according to the specified standard(s):

(*1*) *Encounter diagnoses.* The standard specified in § 170.207(i) or, at a minimum, the version of the standard at § 170.207(a)(4);

(*2*) Cognitive status;

(*3*) Functional status;

(*4*) *Ambulatory setting only.* The reason for referral; and referring or transitioning provider's name and office contact information; and

(*5*) *Inpatient setting only.* Discharge instructions.

(C) Use of the ''unstructured document'' document-level template is prohibited for compliance with the standard adopted at § 170.205(a)(4)).

(iii) *Timeframe configuration.* A user must be able to configure the technology to set the time period within which data would be used to create the export summary or summaries. This must include the ability to enter in a start and end date range as well as the ability to set a date at least three years into the past from the current date.

(iv) *Event configuration.* A user must be able to configure the technology to create an export summary or summaries based on the following user selected events:

(A) A relative date or time (*e.g.,* the first of every month);

(B) A specific date or time (*e.g.,* on 10/24/2015); and

(C) When a user signs a note or an order.

(v) *Location configuration.* A user must be able to configure and set the storage location to which the export summary or export summaries are intended to be saved.

(7) *Data segmentation for privacy—send.* Technology must enable a user to create a summary record formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that is tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1).

(8) *Data segmentation for privacy—receive.* Technology must enable a user to:

(i) Receive a summary record that is tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1);

(ii) Apply document-level tagging and sequester the document from other documents received; and

(iii) View the restricted document (or data), without incorporating the document (or data).

(9) *Care plan.* Technology must enable a user to record, change, access, create, and receive care plan information in accordance with the Care Plan document template in the standard adopted in § 170.205(a)(4).

(c) *Clinical quality measures*—(1) *Clinical quality measures—record and export*—(i) *Record.* For each and every CQM for which the technology is presented for certification, the technology must be able to record all of the data that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of ''patient reason,'' ''system reason,'' or ''medical reason.''

(ii) *Export.* A user must be able to export a data file formatted in accordance with the standard specified at § 170.205(h) for one or multiple patients that includes all of the data captured for each and every CQM to which technology was certified under paragraph (c)(1)(i) of this section. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.

(2) *Clinical quality measures—import and calculate*—(i) *Import.* Enable a user to import a data file in accordance with the standard specified at § 170.205(h) for one or multiple patients and use such data to perform the capability specified in paragraph (c)(2)(ii) of this section. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.

(ii) Technology must be able to calculate each and every clinical quality measure for which it is presented for certification.

(3) [Reserved]

(4) *Clinical quality measures—filter.* (i) Technology must be able to record the data listed in paragraph (c)(4)(iii) of this section in accordance with the identified standards, where specified.

(ii) Technology must be able to filter CQM results at the patient and aggregate levels by each one and any combination of the data listed in paragraph (c)(4)(iii) of this section.

(iii) *Data.* (A) TIN;

(B) NPI;

(C) Provider type;

(D) Patient insurance;

(E) Patient age;

(F) Patient sex in accordance with, at a minimum, the version of the standard specified in § 170.207(n)(1);

(G) Patient race and ethnicity in accordance with, at a minimum, the version of the standard specified in § 170.207(f)(2);

(H) Patient problem list data in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4); and

(I) Practice site address.

(d) *Privacy and security*—(1) *Authentication, access control, and*

authorization. (i) Verify against a unique identifier(s) (*e.g.,* username or number) that a person seeking access to electronic health information is the one claimed; and

(ii) Establish the type of access to electronic health information a user is permitted based on the unique identifier(s) provided in paragraph (d)(1)(i) of this section, and the actions the user is permitted to perform with the technology.

(2) *Auditable events and tamper-resistance*—(i) *Record actions.* Technology must be able to:

(A) Record actions related to electronic health information in accordance with the standard specified in § 170.210(e)(1);

(B) Record the audit log status (enabled or disabled) in accordance with the standard specified in § 170.210(e)(2) unless it cannot be disabled by any user; and

(C) Record the encryption status (enabled or disabled) of electronic health information locally stored on end-user devices by technology in accordance with the standard specified in § 170.210(e)(3) unless the technology prevents electronic health information from being locally stored on end-user devices (see paragraph (d)(7) of this section).

(ii) *Default setting.* Technology must be set by default to perform the capabilities specified in paragraph (d)(2)(i)(A) of this section and, where applicable, paragraph (d)(2)(i)(B) or (C) of this section, or both paragraphs (d)(2)(i)(B) and (C).

(iii) *When disabling the audit log is permitted.* For each capability specified in paragraphs (d)(2)(i)(A) through (C) of this section that technology permits to be disabled, the ability to do so must be restricted to a limited set of users.

(iv) *Audit log protection.* Actions and statuses recorded in accordance with paragraph (d)(2)(i) of this section must not be capable of being changed, overwritten, or deleted by the technology.

(v) *Detection.* Technology must be able to detect whether the audit log has been altered.

(3) *Audit report(s).* Enable a user to create an audit report for a specific time period and to sort entries in the audit log according to each of the data specified in the standards in § 170.210(e).

(4) *Amendments.* Enable a user to select the record affected by a patient's request for amendment and perform the capabilities specified in paragraph (d)(4)(i) or (ii) of this section.

(i) *Accepted amendment.* For an accepted amendment, append the amendment to the affected record or include a link that indicates the amendment's location.

(ii) *Denied amendment.* For a denied amendment, at a minimum, append the request and denial of the request to the affected record or include a link that indicates this information's location.

(5) *Automatic access time-out.* (i) Automatically stop user access to health information after a predetermined period of inactivity.

(ii) Require user authentication in order to resume or regain the access that was stopped.

(6) *Emergency access.* Permit an identified set of users to access electronic health information during an emergency.

(7) *End-user device encryption.* Paragraph (d)(7)(i) or (ii) of this section must be met to satisfy this certification criterion.

(i) Technology that is designed to locally store electronic health information on end-user devices must encrypt the electronic health information stored on such devices after use of the technology on those devices stops.

(A) Electronic health information that is stored must be encrypted in accordance with the standard specified in § 170.210(a)(3).

(B) *Default setting.* Technology must be set by default to perform this capability and, unless this configuration cannot be disabled by any user, the ability to change the configuration must be restricted to a limited set of identified users.

(ii) Technology is designed to prevent electronic health information from being locally stored on end-user devices after use of the technology on those devices stops.

(8) *Integrity.* (i) Create a message digest in accordance with the standard specified in § 170.210(c).

(ii) Verify in accordance with the standard specified in § 170.210(c) upon receipt of electronically exchanged health information that such information has not been altered.

(9) *Accounting of disclosures.* Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(d).

(e) *Patient engagement*—(1) *View, download, and transmit to 3rd party.* (i) Patients (and their authorized representatives) must be able to use technology to view, download, and transmit their health information to a 3rd party in the manner specified below. Access to these capabilities must be online and through a secure channel that ensures all content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

(A) *View.* Patients (and their authorized representatives) must be able to use health IT to view in accordance with the standard adopted at § 170.204(a)(1), at a minimum, the following data:

(*1*) The Common Clinical Data Set (which should be in their English (*i.e.,* non-coded) representation if they associate with a vocabulary/code set).

(*2*) *Ambulatory setting only.* Provider's name and office contact information.

(*3*) *Inpatient setting only.* Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization.

(*4*) *Laboratory test report(s).* Laboratory test report(s), including:

(*i*) The information for a test report as specified all the data specified in 42 CFR 493.1291(c)(1) through (7);

(*ii*) The information related to reference intervals or normal values as specified in 42 CFR 493.1291(d); and

(*iii*) The information for corrected reports as specified in 42 CFR 493.1291(k)(2).

(*5*) Diagnostic image report(s).

(B) *Download.* (*1*) Patients (and their authorized representatives) must be able to use technology to download an ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) in only human readable format, in only the format specified in accordance to the standard adopted at § 170.205(a)(4), or in both formats. The use of the ''unstructured document'' document-level template is prohibited for compliance with the standard adopted at § 170.205(a)(4).

(*2*) When downloaded according to the standard adopted at § 170.205(a)(4), the ambulatory summary or inpatient summary must include, at a minimum, the following data (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set):

(*i*) *Ambulatory setting only.* All of the data specified in paragraph (e)(1)(i)(A)(*1*), (*2*), (*4*), and (*5*) of this section.

(*ii*) *Inpatient setting only.* All of the data specified in paragraphs (e)(1)(i)(A)(*1*), and (*3*) through (*5*) of this section.

(*3*) *Inpatient setting only.* Patients (and their authorized representatives) must be able to download transition of care/referral summaries that were created as a result of a transition of care (pursuant to the capability expressed in

the certification criterion adopted at paragraph (b)(1) of this section).

(C) *Transmit to third party.* Patients (and their authorized representatives) must be able to:

(*1*) Transmit the ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) created in paragraph (e)(1)(i)(B)(*2*) of this section in accordance with at least one of the following:

(*i*) The standard specified in § 170.202(a).

(*ii*) Through a method that conforms to the standard specified at § 170.202(d) and leads to such summary being processed by a service that has implemented the standard specified in § 170.202(a).

(*2*) *Inpatient setting only.* Transmit transition of care/referral summaries (as a result of a transition of care/referral) selected by the patient (or their authorized representative) in accordance with at least one of the following:

(*i*) The standard specified in § 170.202(a).

(*ii*) Through a method that conforms to the standard specified at § 170.202(d) and leads to such summary being processed by a service that has implemented the standard specified in § 170.202(a).

(ii) *Activity history log.* (A) When electronic health information is viewed, downloaded, or transmitted to a third-party using the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section or when an application requests electronic health information using the capability specified at paragraph (e)(1)(iii) of this section, the following information must be recorded and made accessible to the patient:

(*1*) The action(s) (*i.e.,* view, download, transmission, API response) that occurred;

(*2*) The date and time each action occurred in accordance with the standard specified at § 170.210(g);

(*3*) The user who took the action; and

(*4*) Where applicable, the addressee to whom an ambulatory summary or inpatient summary was transmitted.

(B) Technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of this section if it is also certified to the certification criterion adopted at § 170.315(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) is accessible by the patient.

(iii) *Application access.* Patients (and their authorized representatives) must be able to use an application that can interact with the following capabilities. Additionally, the following technical outcomes and conditions must be met through the demonstration of an application programming interface (API) that can respond to requests from other applications for data specified within the Common Clinical Data Set.

(A) *Security.* The API must include a means to establish a trusted connection with the application requesting patient data, including a means for the requesting application to register with the data source, be authorized to request data, and log all interactions between the application and the data source.

(B) *Patient selection.* The API must include a means for the application to query for an ID or other token of a patient's record in order to subsequently execute data requests for that record in accordance with (e)(1)(iii)(C) of this section.

(C) *Data requests, response scope, and return format.* The API must enable and support both of the following data request interactions:

(*1*) *Data-category request.* The API must support syntax that allows it to respond to requests for each of the individual data categories specified in the Common Clinical Data Set and return the full set of data for that data category (according to the specified standards, where applicable) in either XML or JSON.

(*2*) *All-request.* The API must support syntax that allows it to respond to a request for all of the data categories specified in the Common Clinical Data Set at one time and return such data (according to the specified standards, where applicable) in a summary record formatted according to the standard adopted at § 170.205(a)(4).

(D) *Documentation.* The API must include accompanying documentation that contains, at a minimum:

(*1*) API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

(*2*) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(E) *Terms of use.* The terms of use for the API must be provided, including, at a minimum, any associated developer policies and required developer agreements.

(2) *Secure messaging.* Enable a user to send messages to, and receive messages from, a patient in a manner that ensures:

(i) Both the patient (or authorized representative) and technology user are authenticated; and

(ii) The message content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

(f) *Public health*—(1) *Transmission to immunization registries.* (i) Technology must be able to create immunization information for electronic transmission in accordance with:

(A) The standard and applicable implementation specifications specified in § 170.205(e)(4);

(B) At a minimum, the version of the standard specified in § 170.207(e)(3) for historical vaccines; and

(C) At a minimum, the version of the standard specified in § 170.207(e)(4) for administered vaccines.

(ii) Technology must enable a user to request, access, and display a patient's evaluated immunization history and the immunization forecast from an immunization registry in accordance with the standard at § 170.205(e)(4).

(2) *Transmission to public health agencies—syndromic surveillance*—(i) *Ambulatory setting only.* (A) Technology must be able to create syndrome-based public health surveillance information for electronic transmission.

(B) *Optional.* Technology must be able to create syndrome-based public health surveillance information for electronic transmission that contains the following data:

(*1*) Patient demographics;

(*2*) Provider specialty;

(*3*) Provider address;

(*4*) Problem list;

(*5*) Vital signs;

(*6*) Laboratory test values/results;

(*7*) Procedures;

(*8*) Medication list; and

(*9*) Insurance.

(ii) *Inpatient setting only.* Technology must be able to create syndrome-based public health surveillance information for electronic transmission in accordance with the standard (and applicable implementation specifications) specified in § 170.205(d)(4).

(3) *Transmission to public health agencies—reportable laboratory tests and values/results.* Technology must be able to create reportable laboratory tests and values/results for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(g)(2); and

(ii) At a minimum, the versions of the standards specified in § 170.207(a)(4) and (c)(3).

(4) *Transmission to cancer registries.* Technology must be able to create cancer case information for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(i)(2); and

(ii) At a minimum, the versions of the standards specified in § 170.207(a)(4) and (c)(3).

(5) *Transmission to public health agencies—case reporting.* Technology must be able to create case reporting information for electronic transmission in accordance with the standard specified in § 170.205(q)(1).

(6) *Transmission to public health agencies—antimicrobial use and resistance reporting.* Technology must be able to create antimicrobial use and resistance reporting information for electronic transmission in accordance with the standard specified in § 170.205(r)(1).

(7) *Transmission to public health agencies—health care surveys.* Technology must be able to create health care survey information for electronic transmission in accordance with the standard specified in § 170.205(s)(1).

(g) *Design and performance*—(1) *Automated numerator recording.* For each meaningful use objective with a percentage-based measure, technology must be able to create a report or file that enables a user to review the patients or actions that would make the patient or action eligible to be included in the measure's numerator. The information in the report or file created must be of sufficient detail such that it enables a user to match those patients or actions to meet the measure's denominator limitations when necessary to generate an accurate percentage.

(2) *Automated measure calculation.* For each meaningful use objective with a percentage-based measure that is supported by a capability included in a technology, record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.

(3) *Safety-enhanced design.* (i) User-centered design processes must be applied to each capability technology includes that is specified in the following certification criteria: paragraphs (a)(1) through (10) and (18), (20), (22), (23), and (b)(2) through (4) of this section.

(ii) The following information must be submitted on the user-centered design processed used:

(A) Name, description and citation (ULR and/or publication citation) for an industry or federal government standard; or

(B) Name the process(es), provide an outline of the process(es), a short description of the process(es), and an explanation of the reason(s) why use of any of the existing user-centered design standards was impractical.

(iii) The following information/sections from NISTIR 7742 must be submitted for each capability to which user-centered design processes were applied:

(A) Name and version of the product; date and location of the test; test environment; description of the intended users; and total number of participants;

(B) Description of participants, including: sex; age; education; occupation/role; professional experience; computer experience; and product experience;

(C) Description of the user tasks that were tested and association of each task to corresponding certification criteria;

(D) List of the specific metrics captured during the testing, including; task success (%); task failures (%); task standard deviations (%); task performance time; and user satisfaction rating (based on a scale with 1 as very difficult and 5 as very easy);

(E) Test results for each task using metrics listed above in paragraphs (g)(3)(ii)(A) through (D) of this section;

(F) Results and data analysis narrative, including: major test finding; effectiveness; efficiency; satisfaction; and areas for improvement.

(iv) Submit test scenarios used in summative usability testing.

(4) *Quality management system.* (i) For each capability that a technology includes and for which that capability's certification is sought, the use of a Quality Management System (QMS) in the development, testing, implementation, and maintenance of that capability must be identified that is:

(A) Compliant with a QMS established by the Federal government or a standards developing organization; or

(B) Mapped to one or more QMS established by the Federal government or standards developing organization(s).

(ii) If a single QMS was used for applicable capabilities, it would only need to be identified once.

(iii) If different QMS were applied to specific capabilities, each QMS applied would need to be identified.

(5) *Accessibility technology compatibility.* For each capability technology includes that is specified in the certification criteria at paragraphs (a), (b), and (e) of this section, the capability must be compatible with at least one accessibility technology that includes text-to-speech functionality.

(6) *Consolidated CDA creation performance.* The following technical and performance outcomes must be demonstrated related to Consolidated CDA creation. The capabilities required under paragraphs (g)(6)(i) through (iii) of this section can be demonstrated in tandem and do not need to be individually addressed in isolation or sequentially.

(i) *Reference C–CDA match.* Upon the entry of clinical data consistent with the Common Clinical Data Set, the technology must be able to create a data file formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that matches a gold-standard, reference data file.

(ii) *Document-template conformance.* Upon the entry of clinical data consistent with the Common Clinical Data Set, the technology must be able to create a data file formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that demonstrates a valid implementation of each of the following document templates (as applicable to the adopted standard):

(A) *Generally applicable.* CCD; Consultation Note; History and Physical; Progress Note; Care Plan; Transfer Summary; and Referral Note.

(B) *Inpatient setting only.* Discharge Summary.

(iii) *Vocabulary conformance.* Upon the entry of clinical data consistent with the Common Clinical Data Set, the technology must be able to create a data file formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that demonstrates the required vocabulary standards (and value sets) are properly implemented.

(7) *Application access to Common Clinical Data Set.* The following technical outcomes and conditions must be met through the demonstration of an application programming interface (API) that can respond to requests from other applications for data specified within the Common Clinical Data Set.

(i) *Security.* The API must include a means to establish a trusted connection with the application requesting patient data, including a means for the requesting application to register with the data source, be authorized to request data, and log all interactions between the application and the data source.

(ii) *Patient selection.* The API must include a means for the application to query for an ID or other token of a patient's record in order to subsequently execute data requests for that record in accordance with paragraph (g)(7)(iii) of this section.

(iii) *Data requests, response scope, and return format.* The API must enable

and support both of the following data request interactions:

(A) *Data-category request.* The API must support syntax that allows it to respond to requests for each of the individual data categories specified in the Common Clinical Data Set and return the full set of data for that data category (according to the specified standards, where applicable) in either XML or JSON.

(B) *All-request.* The API must support syntax that allows it to respond to a request for all of the data categories specified in the Common Clinical Data Set at one time and return such data (according to the specified standards, where applicable) in a summary record formatted according to the standard adopted at § 170.205(a)(4).

(iv) *Documentation.* The API must include accompanying documentation that contains, at a minimum:

(A) API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

(B) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(v) *Terms of use.* The terms of use for the API must be provided, including, at a minimum, any associated developer policies and required developer agreements.

(8) *Accessibility-centered design.* For each capability that a Health IT Module includes and for which that capability's certification is sought, the use of a health IT accessibility-centered design standard or law in the development, testing, implementation and maintenance of that capability must be identified.

(i) If a single accessibility-centered design standard or law was used for applicable capabilities, it would only need to be identified once.

(ii) If different accessibility-centered design standards and laws were applied to specific capabilities, each accessibility-centered design standard or law applied would need to be identified. This would include the application of an accessibility-centered design standard or law to some capabilities and none to others.

(iii) If no accessibility-centered design standard or law was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

(h) *Transport methods and other protocols*—(1) *Direct Project*—(i) *Applicability Statement for Secure Health Transport.* Technology must be able to send and receive health information in accordance with the standards specified in § 170.202(a).

(ii) *Optional—Applicability Statement for Secure Health Transport and Delivery Notification in Direct.* Technology must be able to send and receive health information in accordance with the standard specified in § 170.202(e)(1).

(2) *Direct Project, Edge Protocol, and XDR/XDM.* Technology must be able to send and receive health information in accordance with:

(i) The standards specified in § 170.202(a);

(ii) The standard specified in § 170.202(b); and

(iii) Both edge protocol methods specified by the standard in § 170.202(d).

(3) *SOAP Transport and Security Specification and XDR/XDM for Direct Messaging.* Technology must be able to send and receive health information in accordance with the standards specified in § 170.202(b) and (c).

(4) *Healthcare provider directory—query request.* In accordance with the standard specified in § 170.202(f)(1), technology must be able to make, at a minimum, the following queries to a directory and subsequently process the response returned:

(i) Query for an individual provider;

(ii) Query for an organizational provider;

(iii) Query for both individual and organizational providers in a single query; and

(iv) Query for relationships between individual and organizational providers.

(v) *Optional—federation.* In accordance with the standard specified in § 170.202(f)(1), technology must be able to process federated responses.

(5) *Healthcare provider directory—query response.* In accordance with the standard specified in § 170.202(f)(1), technology must be able to, at a minimum, respond to the following queries to a directory:

(i) Query for an individual provider;

(ii) Query for an organizational provider;

(iii) Query for both individual and organizational providers in a single query; and

(iv) Query for relationships between individual and organizational providers.

(v) *Optional—federation.* In accordance with the standard specified in § 170.202(f)(1), technology must be able to federate queries to other directories.

(i) *Administrative*—(1) *Electronic submission of medical documentation*—(i) *Document templates.* Health IT must be able to create electronic documents for transmission formatted according to the following standard and applicable implementation specifications adopted at § 170.205(a)(4) and (a)(5)(i). With respect to § 170.205(a)(5)(i):

(A) Health IT must be able to create the following document types regardless of the setting for which it is designed: Diagnostic Imaging Report; Unstructured Document; Enhanced Operative Note Document; Enhanced Procedure Note Document; and Interval Document.

(B) *Ambulatory setting only.* Health IT must be able to create an Enhanced Encounter Document.

(C) *Inpatient setting only.* Health IT must be able to create an Enhanced Hospitalization Document.

(ii) *Digital signature.* (A) *Applying a digital signature.* Technology must be able to apply a digital signature in accordance with the implementation specification adopted at § 170.205(a)(5)(ii) to a document formatted according to the following standard and applicable implementation specifications adopted at § 170.205(a)(4) and (a)(5)(i). It must also be able to demonstrate that it can support the method for delegation of right assertions.

(*1*) The cryptographic module used as part of the technology must: Be validated to meet or exceed FIPS 140–2 Level 1; include a digital signature system and hashing that are compliant with FIPS 186–2 and FIPS 180–2; and store the private key in a FIPS–140–2 Level 1 validated cryptographic module using a FIPS-approved encryption algorithm. This requirement may be satisfied through documentation only.

(*2*) Technology must support multi-factor authentication that meets or exceeds Level 3 assurance as defined in NIST Special Publication 800–63–2.

(*3*) After ten minutes of inactivity, technology must require the certificate holder to re-authenticate to access the private key.

(*4*) If implemented as a software function, the system must clear the plain text private key from the system memory to prevent the unauthorized access to, or use of, the private key when the signing module is deactivated.

(*5*) Technology must record time and date consistent with the standard adopted at § 170.210(g).

(B) *Validating a digital signature.* Technology must be able validate a digital signature that has been applied to a document according to the implementation specification adopted at § 170.205(a)(5)(ii).

(iii) *Author of record level 1.* Using the same system capabilities expressed

in paragraph (i)(1)(ii), technology must be able to apply a digital signature according to the implementation specification adopted at § 170.205(a)(5)(iii) to sign single or bundles of documents a document formatted according to the following standard and applicable implementation specifications adopted at § 170.205(a)(4) and (a)(5)(i).

(iv) *Transactions.* Using the same system capabilities expressed in paragraph (i)(1)(ii) of this section, technology must be able to apply a digital signature according to the implementation specification adopted at § 170.205(a)(5)(iv) to a transaction and include the signature as accompanying metadata in the signed transaction.

(2) [Reserved]

§§ 170.500, 170.501, 170.502, 170.503, 170.504, 170.505, 170.510, 170.520, 170.523, 170.525, 170.530, 170.535, 170.540, 170.545, 170.550, 170.553, 170.555, 170.557, 170.560, 170.565, 170.570, 170.575, and 170.599 [Amended]

■ 12. In subpart E, consisting of §§ 170.500 through 170.599:

■ a. Remove the term ''ONC HIT Certification Program'' and add in its place ''ONC Health IT Certification Program'' wherever it may appear;

■ b. Remove the acronym ''HIT'' and add in its place ''health IT'' wherever it may appear;

■ c. Remove the term ''EHR Module'' and add in its place ''Health IT Module'' wherever it may appear;

■ d. Remove the term ''EHR Modules'' and add in its place ''Health IT Modules'' wherever it may appear; and

■ e. Remove the term ''EHR Module(s)'' and add in its place ''Health IT Module(s)'' wherever it may appear.

■ 13. In § 170.503, revise paragraph (e)(4) to read as follows:

§ 170.503 Requests for ONC–AA status and ONC–AA ongoing responsibilities.

* * * * *

(e) * * *

(4) Verify that ONC–ACBs are performing surveillance as required by and in accordance with § 170.556, § 170.523(k), and their respective annual plans; and

* * * * *

■ 14. Amend § 170.523 by—

■ a. Revising paragraphs (f), (g), (i), and (k); and

■ b. Adding paragraphs (m) and (n).

The additions and revisions read as follows:

§ 170.523 Principles of proper conduct for ONC–ACBs.

* * * * *

(f) Provide ONC, no less frequently than weekly, a current list of Health IT Modules, Complete EHRs, and/or EHR Modules that have been certified that includes, at a minimum:

(1) For the 2015 Edition health IT certification criteria and subsequent editions of health IT certification criteria:

(i) The Health IT Module developer name; product name; product version; developer Web site, physical address, email, phone number, and contact name;

(ii) The ONC–ACB Web site, physical address, email, phone number, and contact name, contact function/title;

(iii) The ATL Web site, physical address, email, phone number, and contact name, contact function/title;

(iv) Location and means by which the testing was conducted (*e.g.*, remotely with health IT developer at its headquarters location);

(v) The date(s) the Health IT Module was tested;

(vi) The date the Health IT Module was certified;

(vii) The unique certification number or other specific product identification;

(viii) The certification criterion or criteria to which the Health IT Module has been certified, including the test procedure and test data versions used, test tool version used, and whether any test data was altered (*i.e.*, a yes/no) and for what purpose;

(ix) The way in which each privacy and security criterion was addressed for the purposes of certification;

(x) The standard or mapping used to meet the quality management system certification criterion;

(xi) The standard(s) or lack thereof used to meet the accessibility-centered design certification criterion;

(xii) *Where applicable*, the hyperlink to access an application programming interface (API)'s documentation and terms of use;

(xiii) *Where applicable*, which certification criteria were gap certified;

(xiv) *Where applicable*, if a certification issued was a result of an inherited certified status request;

(xv) *Where applicable*, the clinical quality measures to which the Health IT Module has been certified;

(xvi) *Where applicable*, any additional software a Health IT Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary;

(xvii) *Where applicable*, the standard(s) used to meet a certification criterion where more than one is permitted;

(xviii) *Where applicable*, any optional capabilities within a certification criterion to which the Health IT Module was tested and certified;

(xix) *Where applicable*, and for each applicable certification criterion, all of the information required to be submitted by Health IT Module developers to meet the safety-enhanced design certification criterion. Each user-centered design element required to be reported must be at a granular level (*e.g.*, task success/failure)); and

(xx) *Where applicable*, for each instance in which a Health IT Module failed to conform to its certification and for which corrective action was instituted under § 170.556 (provided no provider or practice site is identified):

(A) The specific certification criterion to which the technology failed to conform as determined by the ONC–ACB;

(B) The dates surveillance was initiated and when available, completed;

(C) The results of the surveillance (pass rate for each criterion);

(D) The number of sites that were used in surveillance;

(E) The date corrective action began;

(F) When available, the date correction action ended;

(G) A summary of the deficiency or deficiencies identified by the ONC–ACB as the basis for its determination of non-conformance; and

(H) When available, the health IT developer's explanation of the deficiency or deficiencies identified by the ONC–ACB as the basis for its determination of non-conformance.

(2) For the 2014 Edition EHR certification criteria:

(i) The Complete EHR or EHR Module developer name (if applicable);

(ii) The date certified;

(iii) The product version;

(iv) The unique certification number or other specific product identification;

(v) The clinical quality measures to which a Complete EHR or EHR Module has been certified;

(vi) Where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary;

(vii) Where applicable, the certification criterion or criteria to which each EHR Module has been certified; and

(viii) A hyperlink to the test results used to certify the Complete EHRs and/or EHR Modules that can be accessed by the public.

(ix) *Where applicable*, for each instance in which a Complete EHR or EHR Module failed to conform to its certification and for which corrective action was instituted under § 170.556 (provided no provider or practice site is identified):

(A) The specific certification criterion to which the technology failed to conform as determined by the ONC–ACB;

(B) The dates surveillance was initiated and when available, completed;

(C) The results of the surveillance (pass rate for each criterion);

(D) The number of sites that were used in surveillance;

(E) The date corrective action began;

(F) When available, the date corrective action ended;

(G) A summary of the deficiency or deficiencies identified by the ONC–ACB as the basis for its determination of non-conformance; and

(H) When available, the developer's explanation of the deficiency or deficiencies identified by the ONC–ACB as the basis for its determination of non-conformance.

(g) Retain all records related to the certification of Complete EHRs and Health IT Modules for a minimum of 6 years and make them available to HHS upon request;

* * * * *

(i) Submit an annual surveillance plan to the National Coordinator and, in accordance with its surveillance plan, its accreditation, and § 170.556:

(1) Conduct surveillance of certified Complete EHRs and Health IT Modules; and

(2) Report, at a minimum, on a quarterly basis to the National Coordinator the results of its surveillance.

* * * * *

(k) Ensure adherence to the following requirements when issuing any certification and during surveillance of Complete EHRs and Health IT Modules the ONC–ACB has certified:

(1) A Health IT developer must conspicuously include the following on its Web site and in all marketing materials, communications statements, and other assertions related to the Complete EHR or Health IT Module's certification:

(i) The disclaimer ''This [Complete EHR or Health IT Module] is [specify Edition of EHR certification criteria] compliant and has been certified by an ONC–ACB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services. Complaints related to this [Complete EHR or Health IT Module]'s certified capabilities or health IT developer's disclosures should be submitted to *ONC.Certification@hhs.gov*.''

(ii) The information an ONC–ACB is required to report to the National Coordinator under paragraphs (f)(1) and (2) of this section as applicable for the specific Complete EHR or Health IT Module.

(iii) In plain language, a detailed description of all known material information concerning:

(A) Additional types of costs that a user may be required to pay to implement or use the Complete EHR or Health IT Module's capabilities, whether to meet meaningful use objectives and measures or to achieve any other use within the scope of the health IT's certification.

(B) Limitations that a user may encounter in the course of implementing and using the Complete EHR or Health IT Module's capabilities, whether to meet meaningful use objectives and measures or to achieve any other use within the scope of the health IT's certification.

(iv) The types of information required to be disclosed under paragraph (k)(iii) of this section include but are not limited to:

(A) Additional types of costs or fees (whether fixed, recurring, transaction-based, or otherwise) imposed by a health IT developer (or any third-party from whom the developer purchases, licenses, or obtains any technology, products, or services in connection with its certified health IT) to purchase, license, implement, maintain, upgrade, use, or otherwise enable and support the use of capabilities to which health IT is certified; or in connection with any data generated in the course of using any capability to which health IT is certified.

(B) Limitations, whether by contract or otherwise, on the use of any capability to which technology is certified for any purpose within the scope of the technology's certification; or in connection with any data generated in the course of using any capability to which health IT is certified.

(C) Limitations, including but not limited to technical or practical limitations of technology or its capabilities, that could prevent or impair the successful implementation, configuration, customization, maintenance, support, or use of any capabilities to which technology is certified; or that could prevent or limit the use, exchange, or portability of any data generated in the course of using any capability to which technology is certified.

(vi) Health IT self-developers are excluded from the requirements of paragraph (k)(1)(iii) of this section.

(2) A health IT developer must attest as a condition of certification to any certification criterion that it will timely provide in plain writing, conspicuously, and in sufficient detail:

(i) To all customers, prior to providing or entering into any agreement to provide any certified health IT or related product or service (including subsequent updates, add-ons, or additional products or services during the course of an on-going agreement), the information required to be disclosed under paragraph (k)(1) of this section;

(ii) To any person who requests or receives a quotation, estimate, description of services, or other assertion or information from the developer in connection with any certified health IT or any capabilities thereof, the information required to be disclosed under paragraph (k)(1) of this section; and

(iii) To any person, upon request, all or any part of the information required to be disclosed under paragraph (k)(1) of this section.

(3) A certification issued to a pre-coordinated, integrated bundle of Health IT Modules shall be treated the same as a certification issued to a Complete EHR for the purposes of paragraph (k)(1) of this section, except that the certification must also indicate each Health IT Module that is included in the bundle; and

(4) A certification issued to a Complete EHR or Health IT Module based solely on the applicable certification criteria adopted by the Secretary at subpart C of this part must be separate and distinct from any other certification(s) based on other criteria or requirements.

* * * * *

(m) Obtain a record of all adaptations and updates, including changes to user-facing aspects, made to certified Complete EHRs and certified Health IT Modules, on a monthly basis each calendar year.

(n) Submit a list of complaints received to the National Coordinator on a quarterly basis that includes the number of complaints received, the nature/substance of each complaint, and the type of complainant.

■ 15. Amend § 170.550 by—

■ a. Redesignating paragraph (g) as paragraph (k);

■ b. Adding paragraphs (g) and (h); and

■ c. Adding reserved paragraph (i) and paragraph (j).

The additions read as follows:

§ 170.550 Health IT Module certification.

* * * * *

(g) When certifying a Health IT Module to the 2015 Edition health IT

certification criteria, an ONC–ACB must certify the Health IT Module in accordance with the certification criteria at:

(1) Section 170.315(g)(3) if the Health IT Module is presented for certification to one or more listed certification criteria in § 170.315(g)(3);

(2) Section 170.315(g)(4);

(3) Section 170.315(g)(5) if the Health IT Module is presented for certification to one or more of the certification criteria referenced in § 170.315(g)(5);

(4) Section 170.315(g)(6) if the Health IT Module is presented for certification with C–CDA creation capabilities within its scope. If the scope of certification sought includes multiple certification criteria that require C–CDA creation, § 170.315(g)(6) need only be tested in association with one of those certification criteria and would not be expected or required to be tested for each; and

(5) Section 170.315(g)(8).

(h) *Privacy and security certification*—(1) *General rule.* When certifying a Health IT Module to the 2015 Edition health IT certification criteria, an ONC–ACB can only issue a certification to a Health IT Module if the following adopted privacy and security certification criteria have also been met as applicable to the specific capabilities included for certification:

(i) Section 170.315(a) is also certified to the certification criteria adopted at § 170.315(d)(1) through (7);

(ii) Section 170.315(b) is also certified to the certification criteria adopted at § 170.315(d)(1) through (3) and (d)(5) through (8);

(iii) Section 170.315(c) is also certified to the certification criteria adopted at § 170.315(d)(1) through (3);

(iv) Section 170.315(e) is also certified to the certification criteria adopted at § 170.315(d)(1) through (3), (5), and (7);

(v) Section 170.315(f) is also certified to the certification criteria adopted at § 170.315(d)(1) through (3) and (7);

(vi) Section 170.315(h) is also certified to the certification criteria adopted at § 170.315(d)(1) through (3); and

(vii) Section 170.315(i) is also certified to the certification criteria adopted at § 170.315(d)(1) through (3) and (d)(5) through (8).

(2) *Methods to demonstrate compliance with each privacy and security criterion.* One of the following methods must be used to meet each applicable privacy and security criterion listed in paragraph (h)(1) of this section:

(i) Directly, by demonstrating a technical capability to satisfy the applicable certification criterion or certification criteria; or

(ii) Demonstrate, through system documentation sufficiently detailed to enable integration, that the Health IT Module has implemented service interfaces for each applicable privacy and security certification criterion that enable the Health IT Module to access external services necessary to meet the privacy and security certification criterion.

(i) [Reserved]

(j) *Direct Project transport method.* An ONC–ACB can only issue a certification to a Health IT Module for § 170.315(h)(1) if the Health IT Module's certification also includes § 170.315(b)(1).

* * * * *

§ 170.553 [Removed and Reserved]

■ 16. Remove and reserve § 170.553.

■ 17. Add § 170.556 to read as follows:

§ 170.556 In-the-field surveillance and maintenance of certification for Health IT.

(a) *In-the-field surveillance.* Consistent with its accreditation to ISO/IEC 17065 and the requirements of this subpart, an ONC–ACB must initiate surveillance ''in the field'' as necessary to assess whether a certified Complete EHR or certified Health IT Module continues to conform to the requirements of its certification once the certified Complete EHR or certified Health IT Module has been implemented and is in use in a production environment.

(1) *Production environment.* An ONC–ACB's assessment of a certified capability in the field must be based on the use of the capability in a production environment, which means a live environment in which the capabilities have been implemented and are in use.

(2) *Production data.* An ONC–ACB's assessment of a certified capability in the field must be based on the use of the capability with production data unless the use of test data is specifically approved by the National Coordinator.

(b) *Reactive surveillance.* An ONC–ACB must initiate in-the-field surveillance whenever it becomes aware of facts or circumstances that would cause a reasonable person to question a certified Complete EHR or certified Health IT Module's continued conformance to the requirements of its certification.

(1) *Prioritized certification criteria.* An ONC–ACB must initiate in-the-field surveillance if it identifies a trend of non-conformance complaints associated with any certification criteria prioritized by the National Coordinator.

(2) *Review of required disclosures.* When an ONC–ACB performs reactive surveillance under this paragraph (b), it must verify that the requirements of § 170.523(k)(1) have been followed as applicable to the issued certification.

(c) *Randomized surveillance.* An ONC–ACB must initiate in-the-field surveillance for at least 10% of the Complete EHRs and Health IT Modules to which it has issued a certification. Such surveillance must occur on a rolling basis throughout each calendar year.

(1) *Scope.* When an ONC–ACB selects a certified Complete EHR or certified Health IT Module for randomized surveillance under this paragraph, its evaluation of the certified Complete EHR or certified Health IT Module must include all certification criteria prioritized by the National Coordinator under paragraph (b)(1) of this section that are part of the scope of the certification issued to the Complete EHR or Health IT Module.

(2) *Rolling surveillance.* Randomized surveillance required by this paragraph must be completed on an ongoing basis throughout the calendar year.

(3) *Random selection.* An ONC–ACB must randomly select certified Complete EHRs and certified Health IT Modules for surveillance under this paragraph.

(4) *Number and types of locations for in-the-field surveillance.* For each certified Compete EHR or certified Health IT Module selected for randomized surveillance under this paragraph (c), an ONC–ACB must evaluate the certified Complete EHR or certified Health IT Module's capabilities at the lesser of 10 or 5% of locations where the certified Complete EHR or certified Health IT Module is implemented and in use in the field.

(5) *Results of randomized surveillance*—(i) *Successful surveillance results.* A certified Complete EHR or certified Health IT Module will be deemed successful under this paragraph if and only if an ONC–ACB determines that, for each and every certification criterion evaluated, the certified Complete EHR or certified Health IT Module demonstrated continued conformance at 80% or more locations.

(ii) *Deficient surveillance results.* A certified Complete EHR or certified Health IT Module will be deemed deficient under this paragraph if an ONC–ACB determines that, for any certification criterion evaluated, the Complete EHR or Health IT Module demonstrated continued conformance at less than 80% of locations.

(6) *Corrective action plan*—(i) Whenever a Complete EHR or Health IT Module is deemed deficient pursuant to paragraph (c)(5)(ii) of this section, the ONC–ACB must notify the developer of the deficiency and require the developer

to submit a proposed corrective action plan for the applicable certification criterion or certification criteria within 30 days of the date of said notice.

(ii) The ONC–ACB shall provide direction to the developer as to the required elements of the corrective action plan.

(iii) The ONC–ACB shall determine the required elements of the corrective action plan, consistent with its accreditation and any elements specified by the National Coordinator. At a minimum, any corrective action plan submitted by a developer to an ONC–ACB must include:

(A) A description of the identified deficiencies;

(B) An assessment of how widespread or isolated the identified deficiencies may be across the developer's install base for certified Complete EHR or certified Health IT Module;

(C) How the developer will address the identified conformance deficiencies in general and at the locations under which surveillance occurred; and

(D) The timeframe under which corrective action will be completed.

(7) *Certificate suspension procedures in the context of randomized surveillance and corrective action plans.* Under this section and consistent with an ONC–ACB's accreditation to ISO/IEC 17065 and procedures for suspending a certification, an ONC–ACB is permitted to initiate certificate suspension procedures for the Complete EHR or Health IT Module if the developer thereof:

(i) Does not submit a proposed corrective action plan to the ONC–ACB within 30 days of being notified of its deficient surveillance results;

(ii) Does not comply with the ONC–ACB's directions for addressing any aspects of the proposed corrective action plan that do not meet the requirements of the ONC–ACB or the ONC Health IT Certification Program; or

(iii) Does not complete an approved corrective action plan within 6 months of approval of the plan by the ONC–ACB.

(8) *Certificate termination procedures in the context of randomized surveillance.* If a certified Complete EHR or certified Health IT Module's certification has been suspended in the context of randomized surveillance under this paragraph, an ONC–ACB is permitted to initiate certification termination procedures for the Complete EHR or Health IT Module (consistent with its accreditation to ISO/IEC 17065 and procedures for terminating a certification) when the developer has not completed the actions necessary to reinstate the suspended certification.

(9) *Prohibition on consecutive selection for randomized surveillance.* An ONC–ACB is prohibited from selecting a certified Complete EHR or certified Health IT Module for randomized surveillance under this paragraph more than once during any consecutive 12 month period. This limitation does not apply to reactive and other forms of surveillance required under this subpart and the ONC–ACB's accreditation.

(d) *Reporting of surveillance results requirements*—(1) *Rolling submission of in-the-field surveillance results.* The results of in-the-field surveillance under this section must be submitted to the National Coordinator on an ongoing basis throughout the calendar year.

(2) *Confidentiality of locations evaluated.* The contents of an ONC–ACB's surveillance results submitted to the National Coordinator must not include any information that would identify any user or location that participated in or was subject to surveillance.

(3) *Reporting of corrective action plans.* When a corrective action plan is initiated for a Complete EHR or Health IT Module, an ONC–ACB must report the Complete EHR or Health IT Module (and its product identification information) to the National Coordinator in accordance with § 170.523(f)(1)(xix) or (f)(2)(ix), as applicable.

(e) *Relationship to other surveillance requirements.* Nothing in this section shall be construed to limit or constrain an ONC–ACB's general ability to perform surveillance, including in-the-field surveillance, on any certified Complete EHR or certified Health IT Module at any time, as determined appropriate by the ONC–ACB.

Dated: March 18, 2015.

Sylvia M. Burwell,

Secretary.

Note: The following appendix will not appear in the Code of Federal Regulations.

APPENDIX A—2015 EDITION HEALTH IT CERTIFICATION CRITERIA

Proposed CFR citation	Certification criterion	Estimated average developmental hours [270] av. low/av. high	Proposed privacy and security certification requirements [271] (Approach 1)	Conditional certification requirements (§ 170.550)	Gap certification eligibility	Proposed inclusion in 2015 edition base EHR definition	Relationship to the proposed CEHRT [272] definition and proposed EHR Incentive Programs Stage 3 objectives
§ 170.315(a)(1)	Computerized Provider Order Entry (CPOE)—medications.	0/50	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(3) § 170.315(g)(4) § 170.315(g)(8)	§ 170.314(a)(1) § 170.314(a)(18)	Included [273]	Objective 4.
§ 170.315(a)(2)	CPOE—laboratory	1,000/2,000	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(3) § 170.315(g)(4) § 170.315(g)(8)	Not eligible	Included [274]	Objective 4.
§ 170.315(a)(3)	CPOE—diagnostic imaging.	0/50	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(3) § 170.315(g)(4) § 170.315(g)(8)	§ 170.314(a)(1) § 170.314(a)(20)	Included [275]	Objective 4.
§ 170.315(a)(4)	Drug-drug, Drug-allergy Interaction Checks for CPOE.	400/800	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(3) § 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	Objective 3.
§ 170.315(a)(5)	Demographics	500/1,000	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(3) § 170.315(g)(4) § 170.315(g)(8)	Not eligible	Included	No additional relationship beyond the Base EHR Definition.
§ 170.315(a)(6)	Vital Signs, BMI, and Growth Charts.	614/922	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(3) § 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	No relationship.
§ 170.315(a)(7)	Problem List	100/200	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(3) § 170.315(g)(4) § 170.315(g)(8)	Not eligible	Included	No additional relationship beyond the Base EHR Definition.
§ 170.315(a)(8)	Medication List	0/50	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(3) § 170.315(g)(4) § 170.315(g)(8)	§ 170.314(a)(6)	Included	No additional relationship beyond the Base EHR Definition.
§ 170.315(a)(9)	Medication Allergy List	0/50	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(3) § 170.315(g)(4) § 170.315(g)(8)	§ 170.314(a)(7)	Included	No additional relationship beyond the Base EHR Definition.
§ 170.315(a)(10)	Clinical Decision Support	600/1,200	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(3) § 170.315(g)(4) § 170.315(g)(8)	Not eligible	Included	Objective 3.
§ 170.315(a)(11)	Drug-formulary and Preferred Drug List Checks.	310/620	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	Objective 2.
§ 170.315(a)(12)	Smoking Status	100/200	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(4) § 170.315(g)(8)	Not eligible	Included	No additional relationship beyond the Base EHR Definition.
§ 170.315(a)(13)	Image Results	0/20	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(4) § 170.315(g)(8)	§ 170.314(a)(12)	Not included	No relationship.
§ 170.315(a)(14)	Family Health History	100/200	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	CEHRT.[276]
§ 170.315(a)(15)	Family Health History—pedigree.	500/1,200	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	CEHRT.[277]
§ 170.315(a)(16)	Patient List Creation	0/20	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(4) § 170.315(g)(8)	§ 170.314(a)(14)	Not included	No relationship.
§ 170.315(a)(17)	Patient-specific Education Resources.	600/1,200	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	Objective 5.
§ 170.315(a)(18)	Electronic Medication Administration Record.	0/20	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(3) § 170.315(g)(4) § 170.315(g)(8)	§ 170.314(a)(16)	Not included	No relationship.
§ 170.315(a)(19)	Patient Health Information Capture.	500/1,000	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	CEHRT Objective 6.
§ 170.315(a)(20)	Implantable Device List	1,100/1,700	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(3) § 170.315(g)(4) § 170.315(g)(8)	Not eligible	Included	No additional relationship beyond the Base EHR Definition.
§ 170.315(a)(21)	Social, Psychological, and Behavioral Data.	235/470	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	No relationship.
§ 170.315(a)(22)	Decision Support—knowledge artifact.	394/788	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(3) § 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	No relationship.
§ 170.315(a)(23)	Decision Support—service.	229/458	§ 170.315(d)(1) through (d)(7).	§ 170.315(g)(3) § 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	No relationship.
§ 170.315(b)(1)	Transitions of Care	1,550/3,100	§ 170.315(d)(1) through (d)(3) and (d)(5) through (d)(8).	§ 170.315(g)(4) § 170.315(g)(6) § 170.315(g)(8)	Not eligible	Included	Objective 7.
§ 170.315(b)(2)	Clinical Information Reconciliation and Incorporation.	600/1,200	§ 170.315(d)(1) through (d)(3) and (d)(5) through (d)(8).	§ 170.315(g)(3) § 170.315(g)(4) § 170.315(g)(6) § 170.315(g)(8)	Not eligible	Not included	Objective 7.
§ 170.315(b)(3)	Electronic Prescribing	1,050/2,100	§ 170.315(d)(1) through (d)(3) and (d)(5) through (d)(8).	§ 170.315(g)(3) § 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	Objective 2.
§ 170.315(b)(4)	Incorporate Laboratory Tests and Values/Results.	313/626	§ 170.315(d)(1) through (d)(3) and (d)(5) through (d)(8).	§ 170.315(g)(3) § 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	No relationship.
§ 170.315(b)(5)	Transmission of Laboratory Test Reports.	360/720	§ 170.315(d)(1) through (d)(3) and (d)(5) through (d)(8).	§ 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	No relationship.
§ 170.315(b)(6)	Data Portability	800/1,200	§ 170.315(d)(1) through (d)(3) and (d)(5) through (d)(8).	§ 170.315(g)(4) § 170.315(g)(6) § 170.315(g)(8)	Not eligible	Included	No additional relationship beyond the Base EHR Definition.
§ 170.315(b)(7)	Data Segmentation for Privacy—send.	450/900	§ 170.315(d)(1) through (d)(3) and (d)(5) through (d)(8).	§ 170.315(g)(4) § 170.315(g)(6) § 170.315(g)(8)	Not eligible	Not included	No relationship.

APPENDIX A—2015 EDITION HEALTH IT CERTIFICATION CRITERIA—Continued

Proposed CFR citation	Certification criterion	Estimated average developmental hours [270] av. low/av. high	Proposed privacy and security certification requirements [271] (Approach 1)	Conditional certification requirements (§ 170.550)	Gap certification eligibility	Proposed inclusion in 2015 edition base EHR definition	Relationship to the proposed CEHRT [272] definition and proposed EHR Incentive Programs Stage 3 objectives
§ 170.315(b)(8)	Data Segmentation for Privacy—receive.	450/900	§ 170.315(d)(1) through (d)(3) and (d)(5) through (d)(8).	§ 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	No relationship.
§ 170.315(b)(9)	Care Plan	300/500	§ 170.315(d)(1) through (d)(3) and (d)(5) through (d)(8).	§ 170.315(g)(4) § 170.315(g)(6) § 170.315(g)(8)	Not eligible	Not included	No relationship.
§ 170.315(c)(1)	Clinical Quality Measures—record and export.	200/500	§ 170.315(d)(1) through (d)(3).	§ 170.315(g)(4) § 170.315(g)(8)	Not eligible	Included	CEHRT.
§ 170.315(c)(2)	Clinical Quality Measures—import and calculate.	0/200	§ 170.315(d)(1) through (d)(3).	§ 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	No relationship.
§ 170.315(c)(3)	Reserved for Clinical Quality Measures—record.	Reserved	§ 170.315(d)(1) through (d)(3).	§ 170.315(g)(4) § 170.315(g)(8)	Reserved	Reserved	Reserved.[278]
§ 170.315(c)(4)	Clinical Quality Measures—filter.	316/632	§ 170.315(d)(1) through (d)(3).	§ 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	No relationship.
§ 170.315(d)(1)	Authentication, Access Control, Authorization.	0/50	Not applicable (N/A)	§ 170.315(g)(4) § 170.315(g)(8)	§ 170.314(d)(1)	Not included	No relationship.
§ 170.315(d)(2)	Auditable Events and Tamper-resistance.	0/50	N/A	§ 170.315(g)(4) § 170.315(g)(8)	§ 170.314(d)(2)	Not included	No relationship.
§ 170.315(d)(3)	Audit Report(s)	0/50	N/A	§ 170.315(g)(4) § 170.315(g)(8)	§ 170.314(d)(3)	Not included	No relationship.
§ 170.315(d)(4)	Amendments	0/50	N/A	§ 170.315(g)(4) § 170.315(g)(8)	§ 170.314(d)(4)	Not included	No relationship.
§ 170.315(d)(5)	Automatic Access Time-out.	0/50	N/A	§ 170.315(g)(4) § 170.315(g)(8)	§ 170.314(d)(5)	Not included	No relationship.
§ 170.315(d)(6)	Emergency Access	0/50	N/A	§ 170.315(g)(4) § 170.315(g)(8)	§ 170.314(d)(6)	Not included	No relationship.
§ 170.315(d)(7)	End-User Device Encryption.	0/50	N/A	§ 170.315(g)(4) § 170.315(g)(8)	§ 170.314(d)(7)	Not included	No relationship.
§ 170.315(d)(8)	Integrity	0/50	N/A	§ 170.315(g)(4) § 170.315(g)(8)	§ 170.314(d)(8)	Not included	No relationship.
§ 170.315(d)(9)	Accounting of Disclosures	0/20	N/A	§ 170.315(g)(4) § 170.315(g)(8)	§ 170.314(d)(9)	Not included	No relationship.
§ 170.315(e)(1)	View, Download, and Transmit to 3rd Party.	1,000/2,000	§ 170.315(d)(1) through (d)(3), (d)(5), and (d)(7).	§ 170.315(g)(4) § 170.315(g)(6) § 170.315(g)(8)	Not eligible	Not included	Objective 5 Objective 6.
§ 170.315(e)(2)	Secure Messaging	0/50	§ 170.315(d)(1) through (d)(3), (d)(5), and (d)(7).	§ 170.315(g)(4) § 170.315(g)(8)	§ 170.314(e)(3)	Not included	Objective 6.
§ 170.315(f)(1)	Transmission to Immunization Registries.	680/1,360	§ 170.315(d)(1) through (d)(3) and (d)(7).	§ 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	Objective 8.[279]
§ 170.315(f)(2)	Transmission to Public Health Agencies—syndromic surveillance.	480/960	§ 170.315(d)(1) through (d)(3) and (d)(7).	§ 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	Objective 8.
§ 170.315(f)(3)	Transmission to Public Health Agencies—reportable laboratory tests and values/results.	520/1,040	§ 170.315(d)(1) through (d)(3) and (d)(7).	§ 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	Objective 8.
§ 170.315(f)(4)	Transmission to Cancer Registries.	500/1,000	§ 170.315(d)(1) through (d)(3) and (d)(7).	§ 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	Objective 8.
§ 170.315(f)(5)	Transmission to Public Health Agencies—case reporting.	500/1,000	§ 170.315(d)(1) through (d)(3) and (d)(7).	§ 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	Objective 8.
§ 170.315(f)(6)	Transmission to Public Health Agencies—antimicrobial use and resistance reporting.	500/1,000	§ 170.315(d)(1) through (d)(3) and (d)(7).	§ 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	Objective 8.
§ 170.315(f)(7)	Transmission to Public Health Agencies—health care surveys.	500/1,000	§ 170.315(d)(1) through (d)(3) and (d)(7).	§ 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	Objective 8.
§ 170.315(g)(1)	Automated Numerator Recording.	400/800	N/A	§ 170.315(g)(4)	Fact-specific	Not included	CEHRT.
§ 170.315(g)(2)	Automated Measure Calculation.	600/1,200	N/A	§ 170.315(g)(4)	Fact-specific	Not included	CEHRT.
§ 170.315(g)(3)	Safety-Enhanced Design	300/600	N/A	N/A	Fact-specific	Not included	No relationship.
§ 170.315(g)(4)	Quality Management System.	400/800	N/A	N/A	Not eligible	Not included	No relationship.
§ 170.315(g)(5)	Accessibility Technology Compatibility.	800/1400	N/A	N/A	Not eligible	Not included	No relationship.
§ 170.315(g)(6)	Consolidated CDA Creation Performance.	400/1,000	N/A	N/A	Not eligible	Not included	No relationship.
§ 170.315(g)(7)	Application Access to Common Clinical Data Set.	500/1,000	N/A	§ 170.315(g)(4) § 170.315(g)(6) § 170.315(g)(8)	Not eligible	Included	Objective 5 Objective 6.
§ 170.315(g)(8)	Accessibility-Centered Design.	50/100	N/A	N/A	Not eligible	Not included	No relationship.
§ 170.315(h)(1)	Direct Project	0/50	§ 170.315(d)(1) through (d)(3).	§ 170.315(b)(1) § 170.315(g)(4) § 170.315(g)(8)	§ 170.314(b)(1)(i)(A) and § 170.314(b)(2)(ii)(A) § 170.314(h)(1)	Included [280]	No relationship beyond the Base EHR Definition.

APPENDIX A—2015 EDITION HEALTH IT CERTIFICATION CRITERIA—Continued

Proposed CFR citation	Certification criterion	Estimated average developmental hours [270] av. low/av. high	Proposed privacy and security certification requirements [271] (Approach 1)	Conditional certification requirements (§ 170.550)	Gap certification eligibility	Proposed inclusion in 2015 edition base EHR definition	Relationship to the proposed CEHRT [272] definition and proposed EHR Incentive Programs Stage 3 objectives
§ 170.315(h)(2)	Direct Project, Edge Protocol, and XDR/XDM.	0/50	§ 170.315(d)(1) through (d)(3).	§ 170.315(g)(4) § 170.315(g)(8)	§ 170.314(b)(1)(i)(B), § 170.314(b)(2)(ii)(B), and § 170.314(b)(8) [281] 170.314(b)(8) [283] and 170.314(h)(2)	Included [282]	No relationship beyond the Base EHR Definition.
§ 170.315(h)(3)	SOAP Transport and Security Specification and XDR/XDR for Direct Messaging.	0/20	§ 170.315(d)(1) through (d)(3).	§ 170.315(g)(4) § 170.315(g)(8)	§ 170.314(b)(1)(i)(C) and § 170.314(b)(2)(ii)(C) § 170.314(h)(3)	Not included	No relationship.
§ 170.315(h)(4)	Healthcare Provider Directory—query request.	120/240	§ 170.315(d)(1) through (d)(3).	§ 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	No relationship.
§ 170.315(h)(5)	Healthcare Provider Directory—query response.	120/240	§ 170.315(d)(1) through (d)(3).	§ 170.315(g)(4) § 170.315(g)(8)	Not eligible	Not included	No relationship.
§ 170.315(j)(1)	Electronic Submission of Medical Documentation.	1000/200	§ 170.315(d)(1) through (d)(3) and (d)(5) through (d)(8).	§ 170.315(g)(4) § 170.315(g)(6) § 170.315(g)(8)	Not eligible	Not included	No relationship.

[270] Please see section VIII (''Regulatory Impact Statement'') of the preamble for information on how estimated development hours were calculated. To note, certification to the 2014 Edition serves as a foundation for estimating costs. For unchanged certification criteria, in establishing our cost estimates for this proposed rule, we used burden hours multiplied by all health IT developers previously certified to the 2014 Edition version of the certification criteria to account for new entrants. These burden hour estimates are not estimates for development of a new product to meet one or more of these certification criteria. For certification criteria not associated with the EHR Incentive Programs Stage 3, there is a 60% reduction in burden hours. This reduction is due to our estimate that health IT developers would develop 1 product instead of 2.5 products to each of the certification criteria.

[271] We propose to require that an ONC–ACB must ensure that a Health IT Module presented for certification to any of the certification criteria that fall into the regulatory functional categories of § 170.315 for which privacy and security certification requirements apply either pursues approach 1 (detailed in the table) or approach 2: Demonstrate, through system documentation sufficiently detailed to enable integration, that the Health IT Module has implemented service interfaces for each applicable privacy and security certification criterion that enable the Health IT Module to access external services necessary to meet the privacy and security certification criterion.

[272] CMS' CEHRT definition would include the criteria adopted in the Base EHR definition. For more details on the CEHRT definition, please see the CMS EHR Incentive Programs proposed rule published elsewhere in this issue of the **Federal Register.**

[273] Technology needs to be certified to § 170.315(a)(1), (a)(2), or (a)(3).

[274] Technology needs to be certified to § 170.315(a)(1), (a)(2), or (a)(3).

[275] Technology needs to be certified to § 170.315(a)(1), (a)(2), or (a)(3).

[276] Technology needs to be certified to § 170.315(a)(14) or (a)(15).

[277] Technology needs to be certified to § 170.315(a)(14) or (a)(15).

[278] As discussed in the preamble for the ''clinical quality measures—report'' criterion, additional CQM certification policy may be proposed in or with CMS payment rules in CY15. As such, additional CQM certification criteria may be proposed for the Base EHR and/or CEHRT definitions.

[279] For the public health certification criteria in § 170.315(f), technology would only need to be certified to those criteria that are required to meet the options the provider intends to report in order to meet the proposed Objective 8: Public Health and Clinical Data Registry Reporting.

[280] Technology needs to be certified to § 170.315(h)(1) or (h)(2).

[281] Technology must have been certified to both edge protocol methods specified by the standard in § 170.202(d) to be gap certification eligible.

[282] Technology needs to be certified to § 170.315(h)(1) or (h)(2).

[283] Technology must have been certified to both edge protocol methods specified by the standard in § 170.202(d) to be gap certification eligible.

[FR Doc. 2015–06612 Filed 3–20–15; 3:00 pm]

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Part III

Nuclear Regulatory Commission

Privacy Act of 1974; Republication of Systems of Records Notices; Notice

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0072]

Privacy Act of 1974; Republication of Systems of Records Notices

AGENCY: Nuclear Regulatory Commission.

ACTION: Republication of systems of records notices; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has conducted a comprehensive review of all its Privacy Act systems of records notices. The NRC is proposing to adopt a new routine use as a Prefatory Statement of General Routine Uses that will authorize disclosure of information to the National Archives and Records Administration, Office of Government Information Services (OGIS), to the extent necessary to allow OGIS to fulfill its responsibilities to review administrative agency policies, procedures, and compliance with the Freedom of Information Act (FOIA) and offer of mediation services to resolve disputes between persons making FOIA requests and administrative agencies. The NRC is also proposing revisions to NRC 11, ''General Personnel Records (Official Personnel Folder and Related Records)—NRC;'' and NRC 22, ''Personnel Performance Appraisals—NRC.'' The proposed revisions will add a routine use to each of these systems of records that will authorize the disclosure of information to officials of federally-recognized labor organizations when relevant and necessary to their duties of exclusive representation concerning personnel policies, practices, and matters affecting working conditions. The NRC is revising the routine use for NRC 18, ''Office of the Inspector General OIG Investigative Records—NRC. The proposed revision is to reflect that, under the Consolidated Appropriations Act, 2014, the Inspector General of the NRC is authorized in 2014 and subsequent years to exercise the same authorities with respect to the Defense Nuclear Facilities Safety Board, as the Inspector General exercises under the Inspector General Act of 1978 with respect to the NRC.

DATES: Submit comments on the routine uses added to the ''Prefatory Statement of General Routine Uses'' and changes made to NRC Systems of Records NRC–11, ''General Personnel Records (Official Personnel Folder and Related Records)—NRC,'' NRC 18, ''Office of the Inspector General OIG Investigative Records—NRC,'' and NRC–22, ''Personnel Performance Appraisals—NRC'' by April 29, 2015. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date.

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

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0072. 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: Sally Hardy, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–5607; email: *Sally.Hardy@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2015–0072 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–2015–0072.
- *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 *pdr.resource@nrc.gov*. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2015–0072 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information in comment submissions 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, and the NRC does not routinely edit comment submissions to remove identifying or contact information.

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

II. Background

The NRC proposes to revise its Prefatory Statement of General Routine Uses to include a new routine use (8) that will apply to all of its current systems of records, published November 8, 2012 (77 FR 67204), that will authorize disclosure of information to OGIS to the extent necessary to allow OGIS to fulfill its responsibilities under 5 U.S.C. 552(h) to review administrative agency policies, procedures, and compliance with the Freedom of Information Act (FOIA) and offer of mediation services to resolve disputes between persons making FOIA requests and administrative agencies. The NRC is also proposing revisions to NRC 11, ''General Personnel Records (Official Personnel Folder and Related Records)—NRC;'' and NRC 22, ''Personnel Performance Appraisals—NRC.'' The proposed revisions will add a routine use to each of these systems of records that will authorize the disclosure of information to officials of labor organizations recognized under 5

U.S.C. chapter 71 when relevant and necessary to their duties of exclusive representation concerning personnel policies, practices, and matters affecting working conditions. The NRC is proposing revisions to NRC 18, ''Office of the Inspector General (OIG) Investigative Records—NRC. '' The proposed revision is to reflect that, under the Consolidated Appropriations Act, 2014 (Pub. L. 113–76), the NRC Inspector General is authorized to exercise the same authorities with respect to the Defense Nuclear Facilities Safety Board as the NRC Inspector General exercises with respect to the NRC under the Inspector General Act of 1978 (5 U.S.C. App. 3), and that, therefore, records in this system may be used and disclosed in connection with the NRC OIG's exercise of these additional statutory authorities.

A report on these revisions is being sent to the Office of Management and Budget (OMB), Governmental Affairs of U.S. Senate, and the Committee on Government Reform of the U.S House of Representatives as required by the Privacy Act and OMB Circular No. A–130, Appendix I, ''Federal Agency Responsibilities for Maintaining Records About Individuals.''

If changes are made based on the NRC's review of comments received, then the NRC will publish a subsequent notice.

The text of the report, in its entirety, is attached.

Dated at Rockville, Maryland, this 17th day of March, 2015.

For the Nuclear Regulatory Commission.

James Flanagan,

Director, Office of Information Service.

Attachment

Nuclear Regulatory Commission Privacy Act Systems of Records

NRC Systems of Records

1. Parking Permit Records—NRC.
2. Biographical Information Records—NRC.
3. Enforcement Actions Against Individuals—NRC.
4. Conflict of Interest Records—NRC.
5. Contracts Records—NRC.
6. Department of Labor (DOL) Discrimination Cases—NRC.
7. (Revoked.)
8. Employee Disciplinary Actions, Appeals, Grievances, and Complaints Records—NRC.
9. Office of Small Business and Civil Rights Discrimination Complaint Records—NRC.
10. Freedom of Information Act (FOIA) and Privacy Act (PA) Request Records—NRC.
11. General Personnel Records (Official Personnel Folder and Related Records)—NRC.
12. Child Care Subsidy Program Records—NRC.
13. (Revoked.)
14. Employee Assistance Program Records—NRC.
15. (Revoked.)
16. Facility Operator Licensees Records (10 CFR part 55)—NRC.
17. Occupational Injury and Illness Records—NRC.
18. Office of the Inspector General (OIG) Investigative Records—NRC and Defense Nuclear Facilities Safety Board (DNFSB).
19. Official Personnel Training Records—NRC.
20. Official Travel Records—NRC.
21. Payroll Accounting Records—NRC.
22. Personnel Performance Appraisals—NRC.
23. Office of Investigations Indices, Files, and Associated Records—NRC.
24. Property and Supply Records—NRC.
25. Oral History Program—NRC.
26. Transit Subsidy Benefits Program Records—NRC.
27. Radiation Exposure Information and Reporting System (REIRS) Records—NRC.
28. Merit Selection Records—NRC.
29. (Revoked.)
30. (Revoked.)
31. (Revoked.)
32. Office of the Chief Financial Officer Financial Transactions and Debt Collection Management Records—NRC.
33. Special Inquiry Records—NRC.
34. (Revoked.)
35. Drug Testing Program Records—NRC.
36. Employee Locator Records—NRC.
37. Information Security Files and Associated Records—NRC.
38. Mailing Lists—NRC.
39. Personnel Security Files and Associated Records—NRC.
40. Facility Security Access Control Records—NRC.
41. Tort Claims and Personal Property Claims Records—NRC.
42. Strategic Workforce Planning Records—NRC.
43. Employee Health Center Records—NRC.
44. Employee Fitness Center Records—NRC.
45. Electronic Credentials for Personal Identity Verification—NRC.

These systems of records are those systems maintained by the NRC that contain personal information about individuals from which information is retrieved by an individual's name or identifier.

The notice for each system of records states the name and location of the record system, the authority for and manner of its operation, the categories of individuals that it covers, the types of records that it contains, the sources of information in those records, and the routine uses of each system of records. Each notice also includes the business address of the NRC official who will inform interested persons of the procedures whereby they may gain access to and request amendment of records pertaining to them.

The Privacy Act provides certain safeguards for an individual against an invasion of personal privacy by requiring Federal agencies to protect records contained in an agency system of records from unauthorized disclosure, ensure that information is current and accurate for its intended use, and that adequate safeguards are provided to prevent misuse of such information.

Prefatory Statement of General Routine Uses

The following routine uses apply to each system of records notice set forth below which specifically references this Prefatory Statement of General Routine Uses.

1. A record from this system of records which indicates a violation of civil or criminal law, regulation or order may be referred as a routine use to a Federal, State, local or foreign agency that has authority to investigate, enforce, implement or prosecute such laws. Further, a record from this system of records may be disclosed for civil or criminal law or regulatory enforcement purposes to another agency in response to a written request from that agency's head or an official who has been delegated such authority.

2. A record from this system of records may be disclosed as a routine use to a Federal, State, local, or foreign agency to obtain information relevant to an NRC decision concerning hiring or retaining an employee, letting a contract or issuing a security clearance, license, grant or other benefit.

3. A record from this system of records may be disclosed as a routine use to a Federal, State, local, or foreign agency requesting a record that is relevant and necessary to its decision on a matter of hiring or retaining an employee, issuing a security clearance, reporting an investigation of an employee, letting a contract, or issuing a license, grant, or other benefit.

4. A record from this system of records may be disclosed as a routine use in the course of discovery; in presenting evidence to a court, magistrate, administrative tribunal, or grand jury or pursuant to a qualifying order from any of those; in alternative dispute resolution proceedings, such as arbitration or mediation; or in the course of settlement negotiations.

5. A record from this system of records may be disclosed as a routine use to a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

6. A record from this system of records may be disclosed as a routine

use to NRC-paid experts or consultants, and those under contract with the NRC on a ''need-to-know'' basis for a purpose within the scope of the pertinent NRC task. This access will be granted to an NRC contractor or employee of such contractor by a system manager only after satisfactory justification has been provided to the system manager.

7. A record from this system of records may be disclosed as a routine use to appropriate agencies, entities, and persons when: (1) The NRC suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (2) the NRC 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 NRC or another agency or entity) that rely upon the compromised information; and (3) the disclosure to be made to such agencies, entities, and persons is reasonably necessary to assist in connection with the NRC's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

8. To the National Archives and Records Administration, Office of Government Information Services (OGIS), to the extent necessary to allow OGIS to fulfill its responsibilities under 5 U.S.C *552(h), to review administrative agency policies, procedures and compliance with the Freedom of Information Act (FOIA) and offer mediation services to resolve disputes between persons making FOIA requests and administrative agencies*.

NRC–1

SYSTEM NAME:

Parking Permit Records—NRC.

SYSTEM LOCATION:

Administrative Services Center, Office of Administration, NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, and current contractor facility.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

NRC employees and contractors who apply for parking permits for NRC-controlled parking spaces.

CATEGORIES OF RECORDS IN THE SYSTEM:

These records consist of the applications and the revenue collected for the Headquarters' parking facilities. The applications include, but are not limited to, the applicant's name, address, telephone number, length of service, vehicle, rideshare, and handicap information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

31 U.S.C. 3511; 41 CFR 102–74.265 *et seq.,* Parking Facilities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To record amount paid and revenue collected for parking;

b. To contact permit holder;

c. To determine priority for issuance of permits;

d. To provide statistical reports to city, county, State, and Federal Government agencies; and

e. For the routine uses specified in paragraph numbers 1, 4, 5, 6, and 7 in the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper in file folders and on electronic media.

RETRIEVABILITY:

Accessed by name, tag number, and/or permit number.

SAFEGUARDS:

Paper records are maintained in locked file cabinets under visual control of the Administrative Services Center staff. Computer files are maintained on a hard drive, access to which is password protected. Access to and use of these records is limited to those persons whose official duties require access.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html*. Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Administrative Services Center, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Applications submitted by NRC employees and contractors.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–2

SYSTEM NAME:

Biographical Information Records—NRC.

SYSTEM LOCATION:

Office of Public Affairs, NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former Commissioners and senior NRC staff members.

CATEGORIES OF RECORDS IN THE SYSTEM:

These records contain information relating to education and training, employment history, and other general biographical data about the Commissioners and senior NRC staff members, including photographs of Commissioners.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 5841, 5843(a), 5844(a), 5845(a), and 5849.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the

Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To provide information to the press;

b. To provide information to other persons and agencies requesting this information; and

c. For the routine uses specified in paragraph numbers 5, 6, and 7 of the Prefatory Statement of General Routine Uses. Biographies of current Commissioners are available on the NRC's Web site.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on electronic media.

RETRIEVABILITY:

Records are accessed by name.

SAFEGUARDS:

Records are maintained in locked file cabinets. Access to and use of this information is limited to those persons whose official duties require such access.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html*. Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Senior Advisor, Office of Public Affairs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Information is provided by each individual and approved for use by the individual involved.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–3

SYSTEM NAME:

Enforcement Actions Against Individuals—NRC.

SYSTEM LOCATION:

Primary system—Office of Enforcement, NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

Duplicate system—Duplicate systems may exist, in whole or in part, at the NRC Regional Offices at the locations listed in Addendum I, Part 2, and in the Office of the General Counsel, NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals involved in NRC-licensed activities who have been subject to NRC enforcement actions or who have been the subject of correspondence indicating that they are being, or have been, considered for enforcement action.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system includes, but is not limited to, individual enforcement actions, including Orders, Notices of Violations with and without Civil Penalties, Orders Imposing Civil Penalties, Letters of Reprimand, Demands for Information, and letters to individuals who are being or have been considered for enforcement action. Also included are responses to these actions and letters. In addition, the files may contain other relevant documents directly related to those actions and letters that have been issued. Files are arranged numerically by Individual Action (IA) numbers, which are assigned when individual enforcement actions are considered. In instances where only letters are issued, these letters also receive IA numbers. The system includes a computerized database from which information is retrieved by names of the individuals subject to the action and IA numbers.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 2073(e), 2113, 2114, 2167, 2168, 2201(i), 2231, 2282; 10 CFR 30.10, 40.10, 50.5, 50.110, 50.111, 50.120, 60.11, 61.9b, 70.10, 72.12, 110.7b, 110.50, and 110.53; 10 CFR part 2, subpart B; Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 *et seq.*); 10 CFR 19.16(a), 30.7, 40.7, 50.7, 60.9, 70.7, and 72.10; Energy Reorganization Act of 1974, as amended, section 211 (42 U.S.C. 5801 *et seq.*); 5 U.S.C. 2302(a)(2)(A).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To respond to general information requests from the Congress;

b. To deter future violations, certain information in this system of records may be routinely disseminated to the public by means such as: Publishing in the **Federal Register** certain enforcement actions issued to individuals and making the information available in the Public Document Room accessible through the NRC Web site, *www.nrc.gov;*

c. When considered appropriate for disciplinary purposes, information in this system of records, such as enforcement actions and hearing proceedings, may be disclosed to a bar association, or other professional organization performing similar functions, including certification of individuals licensed by NRC or Agreement States to perform specified licensing activities;

d. Where appropriate to ensure the public health and safety, information in this system of records, such as enforcement actions and hearing proceedings, may be disclosed to a Federal or State agency with licensing jurisdiction;

e. To respond to the National Archives and Records Administration or to the General Services Administration for records management inspections conducted under 44 U.S.C. 2904 and 2906; and

f. For all of the routine uses specified in the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper in file folders and on computer media.

RETRIEVABILITY:

Records are accessed by individual action file number or by the name of the individual.

SAFEGUARDS:

Paper records are maintained in lockable file cabinets and are under visual control during duty hours. Access to computer records requires use of proper password and user identification codes. Access to and use of these records is limited to those NRC employees whose official duties require access.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Information in the records is primarily obtained from NRC inspectors and investigators and other NRC employees, individuals to whom a record pertains, authorized representatives for these individuals, and NRC licensees, vendors, other individuals regulated by the NRC, and persons making allegations to the NRC.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–4

SYSTEM NAME:

Conflict of Interest Records—NRC.

SYSTEM LOCATION:

Office of the General Counsel, NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

NRC current and former employees, consultants, special Government employees, and advisory committee members.

CATEGORIES OF RECORDS IN THE SYSTEM:

These records contain information relating to:

a. General biographical data (*i.e.,* name, birth date, home address, position title, home and business telephone numbers, citizenship, educational history, employment history, professional society memberships, honors, fellowships received, publications, licenses, and special qualifications);

b. Financial status (*i.e.,* nature of financial interests and in whose name held, creditors, character of indebtedness, interest in real property, and pension or other retirement interests);

c. Certifications by employees that they and members of their families are in compliance with the Commission's stock ownership regulations;

d. Requests for approval of outside employment by NRC employees and NRC responses thereto;

e. Advice and determinations (*i.e.,* no conflict or apparent conflict of interest, questions requiring resolution, steps taken toward resolution); and

f. Information pertaining to appointment (*i.e.,* proposed period of NRC service, estimated number of days of NRC employment during period of service, proposed pay, clearance status, description of services to be performed and explanation of need for the services, justification for proposed pay, description of expenses to be reimbursed and dollar limitation, and description of Government-owned property to be in possession of appointee).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 CFR 2634–2641, 5801; 5 U.S.C. 7351, 7353; Ethics in Government Act of 1978, as amended (5 U.S.C. app., section 101 *et seq.*); 18 U.S.C. 201–209; 31 U.S.C. 1353; Executive Order (E.O.) 12674 (as modified by E.O. 12731).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To provide the Department of Justice, Office of Personnel Management, Office of Government Ethics, Office of Special Counsel, Office of the Inspector General, and/or Merit Systems Protection Board with information concerning an employee in instances where this office has reason to believe a Federal law may have been violated or where this office desires the advice of the Department, Office, or Board concerning potential violations of Federal law; and

b. For any of the routine uses specified in the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper in file folders and electronic files.

RETRIEVABILITY:

Records are accessed by name.

SAFEGUARDS:

Paper records are maintained in locked file cabinets and computer records are password protected. Access to these records is limited to individuals with a need to know.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be

retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant General Counsel for Legal Counsel, Legislation, and Special Projects, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Information in this system of records either comes from the individual to whom it applies, or is derived from information he or she supplied, or comes from the office to which the individual is to be assigned, other NRC offices, or other persons such as attorneys.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–5

SYSTEM NAME:

Contracts Records—NRC.

SYSTEM LOCATION:

Primary system—Acquisition Management Division, Office of Administration, NRC, Three White Flint North, North Bethesda, Maryland.

Duplicate system—Duplicate systems exist, in part, at the locations listed in Addendum I, Parts 1 and 2, in working files maintained by the assigned contracting office representative and in the NRC's Agencywide Documents Access and Management System (ADAMS).

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Persons who are employed as NRC contractors. NRC employees substantially involved with contracting, such as contracting office representatives and other acquisition officials.

CATEGORIES OF RECORDS IN THE SYSTEM:

These records contain personal information (such as technical qualifications, education, rates of pay, employment history) of contractors and their employees, and other contracting records. They also contain evaluations, recommendations, and reports of NRC acquisition officials, assessment of contractor performance, invoice payment records, and related information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

15 U.S.C. 631, 644; 31 U.S.C. 3511; 13 CFR 124.501–520; 44 U.S.C. 3301; 48 CFR subpart 4.8; 48 CFR part 19.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To provide information to the Federal Procurement Data Center, Department of Health and Human Services, Defense Contract Audit Agency, General Accounting Office, and other Federal agencies for audits and reviews; and

b. For any of the routine uses specified in the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper in file folders and on computer media.

RETRIEVABILITY:

Paper records are accessed by contract number or purchase order number; and are cross-referenced to the automated system that contains the name of the contractor, vendor, contracting office representative, procurement official, and taxpayer identification number (TIN).

SAFEGUARDS:

File folders are maintained in unlocked conserver files in a key code locked room. Access to and use of these records is limited to those persons whose official duties require such access. Access to automated systems is protected by password and roles and responsibilities.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Acquisition Management Division, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.'' Some information was received in confidence and will not be disclosed to the extent that disclosure would reveal confidential business (proprietary) information.

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Information in this system of records comes from the contractor or potential contractor or NRC employee.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Pursuant to 5 U.S.C. 552a(k)(1) and (k)(5), the Commission has exempted portions of this system of records from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f).

NRC–6

SYSTEM NAME:

Department of Labor (DOL) Discrimination Cases—NRC.

SYSTEM LOCATION:

Primary system—Office of Enforcement, NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

Duplicate system—Duplicate systems may exist, in whole or in part, in

enforcement or allegation coordinators' offices at NRC Regional Offices at the addresses listed on Addendum I, Part 2. The duplicate systems in the Regional Offices would ordinarily be limited to the cases filed in each Region.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have filed complaints with DOL concerning alleged acts of discrimination in violation of section 211 of the Energy Reorganization Act.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system consists of documents related to, and provided by, the DOL including copies of complaints, correspondence filed with the Administrative Law Judge assigned to the case, and decisions by the Regional Administrators of DOL's Occupational, Safety, and Health Administration, Administrative Law Judges, and the Administrative Review Board.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 2201, as amended; 42 U.S.C. 2282, as amended; 42 U.S.C. 5851, as amended; 10 CFR 30.7, 40.7, 50.7, 60.9, 61.9, 70.7, and 72.10.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

Any of the routine uses specified in the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

These documents are maintained in a locked filed cabinet. There is no index relating to these documents.

RETRIEVABILITY:

These documents are not kept in alphabetical or date order and are not retrievable by the name of an individual.

SAFEGUARDS:

Paper documents are maintained in locking file cabinets. Access to and use of these documents is limited to those NRC employees whose official duties require access.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.'' Information received from the DOL is treated by DOL as public information and subject to disclosure under applicable laws.

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

The sources of the records include the individuals to whom a record pertains, attorneys for these individuals, defendants, attorneys for the defendants, and DOL.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–7 (Revoked.)

NRC–8

SYSTEM NAME:

Employee Disciplinary Actions, Appeals, Grievances, and Complaints Records—NRC.

SYSTEM LOCATION:

Primary system—Office of the Chief Human Capital Officer, NRC, Three White Flint North, 11601 Landsdown Street, North Bethesda, Maryland.

The Office of the Inspector General (OIG)employee files are located with the NRC's OIG, 11555 Rockville Pike, Rockville, Maryland.

Duplicate system—A duplicate system may be maintained, in whole or in part, in the Office of the General Counsel, NRC, Three White Flint North, 11601 Landsdown Street, North Bethesda, Maryland, and at NRC's Regional Offices at locations listed in Addendum I, Part 2.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former NRC employees, and annuitants who have filed written complaints brought to the Office of the Chief Human Capital Officer's attention or initiated grievances or appeal proceedings as a result of a determination made by the NRC, Office of Personnel Management, and/or Merit Systems Protection Board, or a Board or other entity established to adjudicate such grievances and appeals.

CATEGORIES OF RECORDS IN THE SYSTEM:

Includes all documents related to: disciplinary actions; adverse actions; appeals; complaints, including but not limited to those raised under the agency's prevention of harassment program; grievances; arbitrations; and negative determinations regarding within-grade salary increases. It contains information relating to determinations affecting individuals made by the NRC, Office of Personnel Management, Merit Systems Protection Board, arbitrators or courts of law. The records may include the initial appeal or complaint, letters or notices to the individual, records of hearings when conducted, materials placed into the record to support the decision or determination, affidavits or statements, testimony of witnesses, investigative reports, instructions to an NRC office or division concerning action to be taken to comply with decisions, and related correspondence, opinions, and recommendations.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 3132(a); 5 U.S.C. 3521–3525; 5 U.S.C. 4303, as amended; 5 U.S.C. 7503; 29 U.S.C. 633a; 29 U.S.C. 791; 42 U.S.C. 2000e-16; 42 U.S.C. 2201(d), as amended.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is

compatible with the purpose for which the record was collected under the following routine uses:

a. To furnish information to the Office of Personnel Management and/or Merit Systems Protection Board under applicable requirements related to grievances and appeals;

b. To provide appropriate data to union representatives and third parties (that may include the Federal Services Impasses Panel and Federal Labor Relations Authority) in connection with grievances, arbitration actions, and appeals; and

c. For any of the routine uses specified in the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper and computer media.

RETRIEVABILITY:

Records are retrieved by individual's name.

SAFEGUARDS:

Records are maintained in locked file cabinets and in a password-protected automated system. Access to and use of these records is limited to those persons whose official duties require such access.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Employee and Labor Relations Branch, Office of the Chief Human Capital Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. For OIG employee records: Director, Resource Management and Operations Support, Office of the Inspector General, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.'' Some information was received in confidence and will not be disclosed to the extent that disclosure would reveal a confidential source.

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Individuals to whom the record pertains, NRC, Office of Personnel Management and/or Merit Systems Protection Board officials; affidavits or statements from employees, union representatives, or other persons; testimony of witnesses; official documents relating to the appeal, grievance, or complaint, including but not limited to those raised under the agency's prevention of harassment program; Official Personnel Folder; and other Federal agencies.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–9

SYSTEM NAME:

Office of Small Business and Civil Rights Discrimination Complaint Records—NRC.

SYSTEM LOCATION:

Primary system—Office of Small Business and Civil Rights, NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

Duplicate system—A duplicate system exists, in part, in the Office of the General Counsel, NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Applicants for NRC employment and current and former NRC employees who have initiated EEO counseling and/or filed a formal complaint of employment discrimination under Title VII of the Civil Rights Act, the Age Discrimination in Employment Act of 1967, the Equal Pay Act, Rehabilitation Act and the Genetic Information Nondiscrimination Act (GINA) or Agency Policy for Prohibiting Discrimination Based on Sexual Orientation and Procedures for Filing a Sexual Orientation Discrimination Complaint. Individuals in the United States in education programs or activities receiving Federal financial assistance from the NRC who initiated an informal complaint and/or filed a formal complaint of sex discrimination under Title IX of the Education Amendments Act. Individuals in the United States in programs or activities receiving Federal financial assistance from the NRC who initiated an informal complaint and/or filed a formal complaint of discrimination under Title VI of the Civil Rights Act, the Age Discrimination Act of 1975, Section 504 of the Rehabilitation Act of 1973, and Title IV of the Energy Reorganization Act of 1974, as amended.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system of records may contain copies of written reports by counselors; investigative files; administrative files, including documentation of withdrawn and/or dismissed complaints; complainant's name, title, and grade; types and theories of discrimination alleged; description of action and conditions giving rise to complaints, settlement agreements, and compliance documents; description of corrective and/or remedial actions; description of disciplinary actions, if any; request for hearings, procedural information, and hearing transcripts; procedural information and forms regarding Alternative Dispute Resolution (ADR); Equal Employment Opportunity Commission (EEOC), Genetic Information Nondiscrimination Act (GINA) or Policy for Prohibiting Discrimination Based on Sexual Orientation and Procedures for Filing a Sexual Orientation Discrimination Complaint, Merit System Protection Board (MSPB), Department of Education (ED), and Department of Justice (DOJ) findings, analyses, decisions and orders; final agency decisions and final actions; and notices of intent to file in Federal district court, notices of cases filed in Federal district court, and Federal court decisions.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 2301, 2302; 29 U.S.C. 206(d), as amended; 29 U.S.C. 633a, as amended; 29 U.S.C. 791; 42 U.S.C. 1981; 42 U.S.C. 2000e-16, as amended; 42 U.S.C. 5891; Executive Order (E.O.) 11246 as amended; E.O. 11478 as amended; E.O. 12086, as amended by E.O. 12608; E.O. 12106; E.O. 13166; 10 CFR parts 4 and 5; 29 CFR part 1614.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To furnish information related to discrimination complaints to the EEOC, Office of Personnel Management (OPM), MSPB, DOJ, Dept. of Education, Health and Human Services, Office of Management and Budget, and Congress, under applicable requirements; and

b. For any of the routine uses specified in the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper and electronic media.

RETRIEVABILITY:

Records are accessed by name and docket number.

SAFEGUARDS:

Paper records are maintained in locked file cabinets. Automated system is password protected. Access to and use of these records is limited to those persons whose official duties require such access.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Associate Director, Civil Rights and Diversity Directorate and Associate Director, Small Business, Outreach and Compliance Directorate, Office of Small Business and Civil Rights, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.'' Some information was received in confidence and will not be disclosed to the extent that disclosure would reveal a confidential source.

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Individual to whom the record pertains, counselors, mediators, investigators, NRC staff, Office of the Chief Human Capital Officer, the EEOC, OPM, MSPB, DOJ and/or Dept. of Education officials, affidavits or statements from complainants, testimony of witnesses, and official documents relating to the complaints.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Pursuant to 5 U.S.C. 552a(k)(5), the Commission has exempted portions of this system of records from 5 U.S.C. 552(c)(3), (d), (e)(4)(G), (H), and (I), and (f).

NRC–10

SYSTEM NAME:

Freedom of Information Act (FOIA) and Privacy Act (PA) Request Records—NRC.

SYSTEM LOCATION:

Primary system—FOIA, Privacy, Info Collections Branch, Customer Service Division, Office of Information Services, NRC, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland.

Duplicate system—Duplicate systems may exist, in part, at the locations listed in Addendum I, Parts 1 and 2.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Persons who have made a FOIA or PA request for NRC records.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system contains copies of the written requests from individuals or organizations made under the FOIA or PA, the NRC response letters, and related records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 552 and 552a; 42 U.S.C. 2201, as amended; 10 CFR part 9.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. If an appeal or court suit is filed with respect to any records denied;

b. For preparation of reports required by 5 U.S.C. 552 and 5 U.S.C. 552a;

c. To another Federal agency when consultation or referral is required to process a request; and

d. For any of the routine uses specified in the Prefatory Statement of General Routine Uses. Some of the FOIA records are made publicly available in the Public Documents Room accessible through the NRC Web site, *www.nrc.gov.*

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper, audio and video tapes, and electronic media.

RETRIEVABILITY:

Records are accessed by unique assigned number for each request and by requester's name.

SAFEGUARDS:

Records are maintained in locked file cabinets that are kept in locked rooms. Electronic records are password protected. Access to and use of these records is limited to those persons whose official duties require such access.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance

with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

FOIA/PA Specialist, FOIA, Privacy, Info Collections Branch, Customer Service Division, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the FOIA/PA Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Requests are made by individuals. The response to the request is based upon information contained in NRC records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–11

SYSTEM NAME:

General Personnel Records (Official Personnel Folder and Related Records)—NRC.

SYSTEM LOCATION:

Primary system—For Headquarters and all Senior Executive Service (SES) personnel, Office of the Chief Human Capital Officer, NRC, Three White Flint North, 11601 Landsdown Street, North Bethesda, Maryland. For Regional personnel, at Regional Offices I–IV listed in Addendum I, Part 2. NRC has an interagency agreement with the U.S. Department of the Interior (DOI), National Business Center (NBC), Denver, Colorado, to maintain employee personnel and payroll information.

Duplicate system—Duplicate systems exist, in part, within the organization where an employee actually works for administrative purposes, at the locations listed in Addendum I, Parts 1 and 2.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former NRC employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system contains personnel records that document an individual's Federal career and includes notification of personnel action (SF–50) and documents supporting the action taken; life insurance, thrift savings plan, health benefits and related beneficiary forms; letters of disciplinary action; notices of reductions-in-force; and other records retained in accordance with the Office of Personnel Management's Guide to Personnel Recordkeeping. These records include employment information such as personal qualification statements, resumes, and related documents including information about an individual's birth date, social security number, veterans preference status, tenure, minority group designator, physical handicaps, past and present salaries, grades, position titles; employee locator information identifying home and work address, phone numbers and emergency contacts; and certain medical records related to initial appointment and employment.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C., part III; 5 U.S.C. 4103; 42 U.S.C. 290dd; 42 U.S.C. 2201(d); and Executive Order (E.O.) 9397, as amended by E.O. 13478.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In accordance with an interagency agreement the NRC may disclose records to the DOI/NBC in order to affect the maintenance of electronic personnel records on behalf of the NRC related to its employees.

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses; or, where determined to be appropriate and necessary, the NRC may authorize DOI/NBC to make the disclosure:

a. To the Office of Personnel Management (OPM) and/or Merit Systems Protection Board (MSPB) for making a decision when an NRC employee or former NRC employee questions the validity of a specific document in an individual's record;

b. To a prospective employer of a Government employee. Upon transfer of the employee to another Federal agency, the information is transferred to such agency;

c. To store all personnel actions and related documentation, OPM investigations, Office of the Inspector General investigations, security investigations, determination of eligibility for Federal benefits, employment verification, and to update monthly Enterprise Human Resources Integration data repository;

d. To provide statistical reports to Congress, agencies, and the public on characteristics of the Federal work force;

e. To provide information to the OPM and/or MSPB for review, audit, or reporting purposes;

f. To provide members of the public with the names, position titles, grades, salaries, appointments (temporary or permanent), and duty stations of employees;

g. For medical records, to provide information to the Public Health Service in connection with Health Maintenance Examinations and to other Federal agencies responsible for Federal benefit programs administered by the Department of Labor (Office of Workers' Compensation Programs) and the OPM;

h. To disclose information to officials of labor organizations recognized under 5 U.S.C. chapter 71 when relevant and necessary to their duties of exclusive representation concerning personnel policies, practices, and matters affecting working conditions; and

i. For any of the routine uses specified in the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper in file folders and on electronic media. Effective November 2009, the Official Personnel Folders (OPFs) are maintained electronically in OPM's Enterprise Human Resources Interface.

RETRIEVABILITY:

Records are retrieved by name and/or social security number.

SAFEGUARDS:

The OPFs are stored electronically in a secure OPM central repository, with role-based security for access to the records and audit trail for all user activity. Paper documents are maintained in lockable file cabinets. Automated systems are password protected. Access to and use of these records is limited to those persons whose official duties require such access.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC

Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

For Headquarters and all NRC SES employees—Associate Director for Human Resources Operations and Policy, Office of the Chief Human Capital Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For Region I–IV non-SES employees—The appropriate Regional Personnel Officer at the locations listed in Addendum I, Part 2.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Information in this system of records comes from the individual to whom it applies; is derived from information supplied by that individual; or is provided by agency officials, other Federal agencies, universities, other academic institutions, or persons, including references, private and Federal physicians, and medical institutions.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Pursuant to 5 U.S.C. 552a(k)(5) and (k)(6), the Commission has exempted portions of this system of records from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f).

NRC–12

SYSTEM NAME:

Child Care Subsidy Program Records—NRC.

SYSTEM LOCATION:

FEEA Child Care Service Inc., 3333 S. Wadsworth Boulevard, Suite 300, Lakewood, Colorado (or current contractor facility).

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

NRC employees who voluntarily apply for child care subsidy.

CATEGORIES OF RECORDS IN THE SYSTEM:

These records include application forms for child care subsidy containing personal information about the employee (parent), their spouse (if applicable), their child/children, and their child care provider, including name, social security number, employer, grade, home and work telephone numbers, home and work addresses, total family income, name of child on whose behalf the parent is applying for subsidy, child's date of birth; information on child care providers used, including name, address, provider license number and State where issued, child care cost, and provider tax identification number; and copies of IRS Form 1040 or 1040A for verification purposes.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

40 U.S.C. 590(g); 5 CFR 792.201–206; Executive Order (E.O.) 9397, as amended by E.O. 13478.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To the Office of Personnel Management to provide statistical reports; and

b. For any of the routine uses specified in the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSITION OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper and electronic media at the current contractor site.

RETRIEVABILITY:

Information may be retrieved by employee name or social security number.

SAFEGUARDS:

When not in use by an authorized person, paper records are stored in lockable file cabinets and computer records are protected by the use of passwords.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER AND ADDRESS:

Associate Director for Human Resources Operations and Policy, Office of the Chief Human Capital Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Information is obtained from NRC employees who apply for child care subsidy and their child care provider.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–13 (Revoked.)

NRC–14

SYSTEM NAME:

Employee Assistance Program Records—NRC.

SYSTEM LOCATION:

Office of the Chief Human Capital Officer, NRC, Two White Flint North,

11545 Rockville Pike, Rockville, Maryland, and current contractor facility.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

NRC employees or family members who have been counseled by or referred to the Employee Assistance Program (EAP) for problems relating to alcoholism, drug abuse, job stress, chronic illness, family or relationship concerns, and emotional and other similar issues.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system contains records of NRC employees or their families who have participated in the EAP and the results of any counseling or referrals which may have taken place. The records may contain information as to the nature of each individual's problem, subsequent treatment, and progress.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 7901; 21 U.S.C. 1101–1181; 42 U.S.C. chapter 6A, Subchapter III–A; 44 U.S.C. 3101; 44 U.S.C. 3301; 5 CFR 792.101–105.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. For statistical reporting purposes; and

b. Any disclosure of information pertaining to an individual will be made in compliance with the Confidentiality of Alcohol and Drug Abuse Patient Records regulations, 42 CFR part 2, as authorized by 42 U.S.C. 290dd-2, as amended.

c. For the routine uses specified in paragraph number 7 of the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper in file folders and on electronic media.

RETRIEVABILITY:

Information accessed by the EAP identification number and name of the individual.

SAFEGUARDS:

Files are maintained in a safe under the immediate control of the Employee Assistance Program Manager and the current EAP contractor. Case files are maintained in accordance with the confidentiality requirements of P.L. 93–282, any NRC-specific confidentiality regulations, and the Privacy Act of 1974.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Employee Assistance Program Manager, Office of the Chief Human Capital Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Information compiled by the Employee Assistance Program Manager, and the Employee Assistance Program contractor during the course of counseling with an NRC employee or members of the employee's family.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–15 (Revoked.)

NRC–16

SYSTEM NAME:

Facility Operator Licensees Records (10 CFR part 55)—NRC.

SYSTEM LOCATION:

For power reactors, at the appropriate Regional Office at the address listed in Addendum I, Part 2; for non-power (test and research) reactor facilities, at the Operator Licensing and Training Branch, Division of Inspection and Regional Support, Office of Nuclear Reactor Regulation, NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The Operator Licensing Tracking System (OLTS) is located at NRC Headquarters and is accessible by the four Regional Offices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals licensed under 10 CFR part 55, new applicants whose applications are being processed, and individuals whose licenses have expired.

CATEGORIES OF RECORDS IN THE SYSTEM:

These records contain information pertaining to 10 CFR part 55 applicants for a license, licensed operators, and individuals who previously held licenses. This includes applications for a license, license and denial letters, and related correspondence; correspondence relating to actions taken against a licensee; 10 CFR 50.74 notifications; certification of medical examination and related medical information; fitness for duty information; examination results and other docket information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 2131–2141; 10 CFR part 55.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To determine if the individual meets the requirements of 10 CFR part 55 to take an examination or to be issued an operator's license;

b. To provide researchers with information for reports and statistical evaluations related to selection, training, and examination of facility operators;

c. To provide examination, testing material, and results to facility management; and

d. For any of the routine uses specified in paragraph numbers 1, 2, 4, 5, 6, and 7 of the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper in file folders and logs, and on electronic media.

RETRIEVABILITY:

Records are accessed by name and docket number.

SAFEGUARDS:

Maintained in locked file cabinets or an area that is locked. Computer files are password protected. Access to and use of these records is limited to those persons whose official duties require such access based on roles and responsibilities.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Operator Licensing and Training Branch, Division of Inspection and Regional Support, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Information in this system comes from the individual applying for a license, the 10 CFR part 50 licensee, a licensed physician, and NRC and contractor staff.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–17

SYSTEM NAME:

Occupational Injury and Illness Records—NRC.

SYSTEM LOCATION:

Primary system—For Headquarters personnel: Part 1 (Workers' Compensation Program)—Office of the Chief Human Capital Officer, NRC, Three White Flint North, North Bethesda, Maryland. Part 2 (Occupational Safety and Health Program)—Office of Administration, NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

For Regional personnel, at each of the Regional Offices listed in Addendum I, Part 2.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former NRC employees with a reported occupational injury or illness.

CATEGORIES OF RECORDS IN THE SYSTEM:

These records contain information regarding the location and description of the injury or illness, treatment, and disposition as well as copies of Office of Workers' Compensation Program claim forms.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 7902, as amended; 29 U.S.C. 657(c), as amended; Executive Order (E.O.) 12196 as amended; 29 CFR parts 1904, 1960.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To prepare periodic statistical reports on employees' health and injury status for transmission to and review by the Department of Labor;

b. For transmittal to the Secretary of Labor or an authorized representative under duly promulgated regulations;

c. For transmittal to the Office of Personnel Management, Merit Systems Protection Board, and/or Equal Employment Opportunity Commission as required to support individual claims; and

d. For any of the routine uses specified in the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper and electronic media.

RETRIEVABILITY:

Records retrieved by employee name or assigned claim number.

SAFEGUARDS:

Paper records are locked file cabinets under the visual control of the responsible staff. Electronic records are password protected. Access to and use of these records is limited to those persons whose official duties require such access.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

For Headquarters—Benefits Officer, Human Resources Operations and Policy, Office of the Chief Human Capital Officer, and Part 2—Safety and Occupational Health Manager, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. For Region I–IV—The appropriate Human Resources Team Leader at the locations listed in Addendum I, Part 2.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

NRC Health Center; NRC Headquarters and Regional Office reports; and forms with original information largely supplied by the employees or their representative, supervisors, witnesses, medical personnel, etc.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–18

SYSTEM NAME:

Office of the Inspector General (OIG) Investigative Records—NRC and Defense Nuclear Facilities Safety Board (DNFSB).

SYSTEM LOCATION:

Office of the Inspector General, NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals and entities referred to in complaints or actual investigative cases, reports, accompanying documents, and correspondence prepared by, compiled by, or referred to the OIG.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system comprises five parts: (1) An automated Investigative Database Program containing reports of investigations, inquiries, and other reports closed since 1989; (2) paper files of all OIG and predecessor Office of Inspector and Auditor (OIA) reports, correspondence, cases, matters, memoranda, materials, legal papers, evidence, exhibits, data, and work papers pertaining to all closed and pending investigations, inquiries, and other reports; (3) paper index card files of OIG and OIA cases closed from 1970 through 1989; (4) an automated Allegations Tracking System that includes allegations referred to the OIG between 1985 and 2005, whether or not the allegation progressed to an investigation, inquiry, or other report, and dates that the investigation, inquiry, or other report, was opened and closed; and (5) an automated Investigative Management System that includes allegations referred to the OIG from 1985 forward, whether or not the allegation progressed to an investigation, inquiry or other report, and dates that an investigation, inquiry or other report was opened and closed and reports, correspondence, cases, matters, memoranda, materials, legal papers, evidence, exhibits, data and work papers pertaining to these cases.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Inspector General Act of 1978, as amended, 5 U.S.C. app. 3; and the Consolidated Appropriations Act, 2014

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, OIG may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To any Federal, State, local, tribal, or foreign agency, or other public authority responsible for enforcing, investigating, or prosecuting violations of administrative, civil, or criminal law or regulation if that information is relevant to any enforcement, regulatory, investigative, or prosecutorial responsibility of the receiving entity when records from this system of records, either by themselves or in combination with any other information, indicate a violation or potential violation of law, whether administrative, civil, criminal, or regulatory in nature.

b. To public or private sources to the extent necessary to obtain information from those sources relevant to an OIG investigation, audit, inspection, or other inquiry.

c. To a court, adjudicative body before which NRC or DNFSB is authorized to appear, Federal agency, individual or entity designated by NRC or DNFSB or otherwise empowered to resolve disputes, counsel or other representative, or witness or potential witness when it is relevant and necessary to the litigation if any of the parties listed below is involved in the litigation or has an interest in the litigation:

1. NRC or DNFSB, or any component of NRC or DNFSB;

2. Any employee of NRC or DNFSB where the NRC or DNFSB or the Department of Justice has agreed to represent the employee; or

3. The United States, where NRC or DNFSB determines that the litigation is likely to affect the NRC or DNFSB or any of their components.

d. To a private firm or other entity with which OIG or NRC or DNFSB contemplates it will contract or has contracted for the purpose of performing any functions or analyses that facilitate or are relevant to an investigation, audit, inspection, inquiry, or other activity related to this system of records, to include to contractors or entities who have a need for such information or records to resolve or support payment to the agency. The contractor, private firm, or entity needing access to the records to perform the activity shall maintain Privacy Act safeguards with respect to information. A contractor, private firm, or entity operating a system of records under 5 U.S.C. 552a(m) shall comply with the Privacy Act.

e. To another agency to the extent necessary for obtaining its advice on any matter relevant to an OIG investigation, audit, inspection, or other inquiry related to the responsibilities of the OIG.

f. To the National Archives and Records Administration or to the General Services Administration for records management inspections conducted under 44 U.S.C. 2904 and 2906.

g. For any of the routine uses specified in the Prefatory Statement of General Routine Uses.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosure Pursuant to 5 U.S.C. 552a(b)(12):

Disclosure of information to a consumer reporting agency is not considered a routine use of records. Disclosures may be made from this system to ''consumer reporting agencies'' as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f) (1970)) or the Federal Claims Collection Act of 1966, as amended (31 U.S.C. 3701(a)(3) (1996)).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Information is maintained on index cards, in paper files, and on electronic media.

RETRIEVABILITY:

Information is retrieved from the Investigative Database Program by the name of an individual, by case number, or by subject matter. Information in the paper files backing up the Investigative Database Program and older cases closed by 1989 is retrieved by subject matter and/or case number, not by individual identifier. Information is retrieved from index card files for cases closed before 1989 by the name or numerical identifier of the individual or entity under investigation or by subject matter. Information in both the Allegations Tracking System and the

Investigative Management System is retrieved by allegation number, case number, or name.

SAFEGUARDS:

Access to the automated Investigative Database Program is password protected. Index card files for older cases (1970–1989) are maintained in secure office facilities. Both the Allegations Tracking System and the Investigative Management System are accessible from terminals that are double-password-protected. Paper files backing up the automated systems and older case reports and work papers are maintained in approved security containers and locked filing cabinets in a locked room; associated indices, records, diskettes, tapes, etc., are stored in locked metal filing cabinets, safes, storage rooms, or similar secure facilities. All records in this system are available only to authorized personnel who have a need to know and whose duties require access to the information.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Inspector General for Investigations, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.'' Information classified under Executive Order 12958 will not be disclosed. Information received in confidence will be maintained under the Inspector General Act, 5 U.S.C. app. 3, and the Commission's Policy Statement on Confidentiality, Management Directive 8.8, ''Management of Allegations.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

The information is obtained from sources including, but not limited to, the individual record subject; NRC officials and employees; employees of Federal, State, local, and foreign agencies; and other persons.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Under 5 U.S.C. 552a(j)(2), the Commission has exempted this system of records from subsections (c)(3) and (4), (d)(1)–(4), (e)(1)–(3), (5), and (8), and (g) of the Act. This exemption applies to information in the system that relates to criminal law enforcement and meets the criteria of the (j)(2) exemption. Under 5 U.S.C. 552a(k)(1), (k)(2), (k)(5), and (k)(6), the Commission has exempted portions of this system of records from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f).

NRC–19

SYSTEM NAME:

Official Personnel Training Records—NRC.

SYSTEM LOCATION:

Primary system located at the NRC's current contractor facility on behalf of the Office of the Chief Human Capital Officer, NRC, Three White Flint North, 11601 Landsdown Street, North Bethesda, Maryland.

The Office of the Inspector General (OIG) employee files are located with the OIG at NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

Duplicate system—Duplicate systems exist, in part, at the Technical Training Center, Regional Offices, and within the organization where the NRC employee works, at the locations listed in Addendum I, Parts 1 and 2.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who applied or were selected for NRC, other Government, or non-Government training courses or programs.

CATEGORIES OF RECORDS IN THE SYSTEM:

These records contain information relating to an individual's educational background and training courses including training requests and authorizations, evaluations, supporting documentation, and other related personnel information, including but not limited to, an individual' name, address, telephone number, position title, organization, and grade.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 3396; 5 U.S.C. 4103; Executive Order (E.O.) 9397, as amended by E.O. 13478; E.O. 11348, as amended by E.O. 12107; 5 CFR parts 410 and 412.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. Extracted from the records and made available to the Office of Personnel Management; other Federal, State, and local government agencies; educational institutions and training facilities for purposes of enrollment and verification of employee attendance and performance; and

b. Disclosed for the routine uses specified in paragraph numbers 5, 6, and 7 of the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper in file folders and on electronic media.

RETRIEVABILITY:

Information is accessed by name, user identification number, course number, or course session number.

SAFEGUARDS:

Electronic records are maintained in a password protected computer system. Paper is maintained in lockable file cabinets and file rooms. Access to and use of these records is limited to those persons whose official duties require such access, with the level of access controlled by roles and responsibilities.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for

Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Associate Director for Training and Development, Office of the Chief Human Capital Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. For OIG employee records: Director, Resource Management and Operations Support, Office of the Inspector General, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Information is provided by the subject individual, the employee's supervisor, and training groups, agencies, or educational institutions and learning activities.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–20

SYSTEM NAME:

Official Travel Records—NRC.

SYSTEM LOCATION:

Primary system—Division of the Controller, Office of the Chief Financial Officer, NRC, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland. NRC has an interagency agreement with DEVA Consulting Group, Rockville, Maryland, to review and approve vouchers as of June 2013. The Office of International Programs, NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, maintains the passport and visa records.

Duplicate system—Duplicate systems may exist, in part, within the organization where an employee actually works for administrative purposes, at the locations listed in Addendum I, Parts 1 and 2.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Prospective, current, and former NRC employees; consultants; and invitational travelers.

CATEGORIES OF RECORDS IN THE SYSTEM:

These records contain requests and authorizations for official travel, travel vouchers, passports, visas, and related documentation; charge card applications, terms and conditions for use of charge cards, charge card training documentation, monthly reports regarding accounts, credit data, and related documentation; all of which may include, but are not limited to, an individual's name, address, social security number, and telephone numbers.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. part III, subpart D, chapter 57; 31 U.S.C. 716; 41 U.S.C. subtitle II, chapter 61; 41 CFR part 102–118; Executive Order (E.O.) 9397, as amended by E.O. 13478.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In accordance with the interagency agreement, NRC may disclose records to DEVA Consulting Group to cross-service travel voucher reimbursements on behalf of the NRC. Specifically, DEVA Consulting Group will examine and pay travel vouchers and maintain the official agency record.

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses; or, where determined to be appropriate and necessary, the NRC may authorize DEVA Consulting Group to make the disclosure:

a. To the U.S. Treasury for payment;

b. To the Department of State or an embassy for passports or visas;

c. To the General Services Administration and the Office of Management and Budget for required periodic reporting;

d. To the charge card issuing bank;

e. To the Department of Interior, National Business Center, for collecting severe travel card delinquencies by employee salary offset;

f. To a consumer reporting agency to obtain credit reports; and

g. For any of the routine uses specified in the Prefatory Statement of General Routine Uses.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosure Pursuant to 5 U.S.C. 552a(b)(12):

Disclosures of information to a consumer reporting agency, other than to obtain credit reports, are not considered a routine use of records. Disclosures may be made from this system to ''consumer reporting agencies'' as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f) (1970)) or the Federal Claims Collection Act of 1966, as amended (31 U.S.C. 3701(a)(3) (1996)).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper in file folders, on electronic media, and on magnetic tape.

RETRIEVABILITY:

Records are accessed by name, social security number, authorization number, and voucher payment schedule number.

SAFEGUARDS:

Maintained in key locked file cabinets and in conserver files in a passcode locked room. Passports and visas are maintained in a locked file cabinet. For electronic records, an identification number, a password, and assigned access to specific programs are required in order to retrieve information.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Travel Operations Branch, Division of the Controller, Office of the Chief Financial Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. For passport and visa

records: Chief, International Operations Branch, Office of International Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Information is provided by the individual, NRC staff, NRC contractors, charge card issuing bank, the consumer reporting agency, outside transportation agents, Department of State, and embassies.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–21

SYSTEM NAME:

Payroll Accounting Records—NRC.

SYSTEM LOCATION:

Primary system—Division of the Controller, Office of the Chief Financial Officer, NRC, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland. NRC has an interagency agreement with the Department of the Interior's National Business Center (DOI/NBC), Federal Personnel/Payroll System (FPPS), in Denver, Colorado, to maintain electronic personnel information and perform payroll processing activities for its employees as of November 2, 2003.

Duplicate system—Duplicate systems exist, in part, within the organization where the employee actually works for administrative purposes, at the locations listed in Addendum I, Parts 1 and 2.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former NRC employees, including special Government employees (*i.e.* consultants).

CATEGORIES OF RECORDS IN THE SYSTEM:

Pay, leave, benefit enrollment and voluntary allowance deductions, and labor activities, which includes, but is not limited to, an individual's name and social security number.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

26 CFR 31.6011(b)(–2), 31.6109–1; 5 U.S.C. 6334; 5 U.S.C. part III, subpart D; 31 U.S.C. 716; 31 U.S.C., subtitle III, chapters 35 and 37; Executive Order (E.O.) 9397, as amended by E.O. 13478.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In accordance with an interagency agreement the NRC may disclose records to the DOI/NBC/FPPS in order to effect all financial transactions on behalf of the NRC related to employee pay. Specifically, the DOI/NBC's FPPS may affect employee pay or deposit funds on behalf of NRC employees, and/or it may withhold, collect or offset funds from employee salaries as required by law or as necessary to correct overpayment or amounts due.

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses; or, where determined to be appropriate and necessary, the NRC may authorize DOI/NBC to make the disclosure:

a. For transmittal of data to U.S. Treasury to effect issuance of paychecks to employees and consultants and distribution of pay according to employee directions for savings bonds, allotments, financial institutions, and other authorized purposes including the withholding and reporting of Thrift Savings Plan deductions to the Department of Agriculture's National Finance Center;

b. For reporting tax withholding to Internal Revenue Service and appropriate State and local taxing authorities;

c. For FICA and Medicare deductions to the Social Security Administration;

d. For dues deductions to labor unions;

e. For withholding for health insurance to the insurance carriers by the Office of Personnel Management;

f. For charity contribution deductions to agents of charitable institutions;

g. For annual W–2 statements to taxing authorities and the individual;

h. For transmittal to the Office of Management and Budget for financial reporting;

i. For withholding and reporting of retirement, tax levies, bankruptcies, garnishments, court orders, re-employed annuitants, and life insurance information to the Office of Personnel Management;

j. For transmittal of information to State agencies for unemployment purposes;

k. For transmittal to the Office of Child Support Enforcement, Administration for Children and Families, Department of Health and Human Services Federal Parent Locator System and Federal Tax Offset System for use in locating individuals and identifying their income sources to establish paternity, establish and modify orders of support, and for enforcement action;

l. For transmittal to the Office of Child Support Enforcement for release to the Social Security Administration for verifying social security numbers in connection with the operation of the Federal Parent Locator System by the Office of Child Support Enforcement;

m. For transmittal to the Office of Child Support Enforcement for release to the Department of Treasury for the purpose of administering the Earned Income Tax Credit Program (Section 32, Internal Revenue Code of 1986) and verifying a claim with respect to employment in a tax return;

n. To the National Archives and Records Administration or to the General Services Administration for records management inspections conducted under 44 U.S.C. 2904 and 2906;

o. Time and labor data are used by the NRC as a project management tool in various management records and reports (*i.e.* work performed, work load projections, scheduling, project assignments, budget), and for identifying reimbursable and fee billable work performed by the NRC; and

p. For any of the routine uses specified in the Prefatory Statement of General Routine Uses.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosure pursuant to 5 U.S.C. 552a(b)(12):

Disclosures of information to a consumer reporting agency are not considered a routine use of records. Disclosures may be made from this system to ''consumer reporting agencies'' as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f) (1970)) or the Federal Claims Collection Act of 1966, as amended (31 U.S.C. 3701(a)(3) (1996)).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Information is maintained on electronic media (stored in memory, on disk, and magnetic tape), on microfiche, and in paper copy.

Electronic payroll, time, and labor records prior to November 2, 2003, are maintained in the Human Resources Management System (HRMS), the PAY PERS Historical database reporting system, and on microfiche at NRC. Electronic payroll records from November 2, 2003, forward are maintained in the DOI/NBC's FPPS in Denver, Colorado. Time and labor records are maintained in the HRMS at NRC.

RETRIEVABILITY:

Information is accessed by employee identification number, name and social security number.

SAFEGUARDS:

Records are maintained in buildings where access is controlled by a security guard force. File folders, microfiche, tapes, and disks, including backup data, are maintained in secured locked rooms and file cabinets after working hours. All records are in areas where access is controlled by keycard and is limited to NRC and contractor personnel who need the information to perform their official duties. Access to computerized records requires use of proper passwords and user identification codes.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Payroll and Payments Branch, Division of the Controller, Office of the Chief Financial Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Information in this system of records is obtained from sources, including but not limited to, the individual to whom it pertains, the Office of the Chief Human Capital Officer and other NRC officials, and other agencies and entities.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–22

SYSTEM NAME:

Personnel Performance Appraisals—NRC.

SYSTEM LOCATION:

Primary system—Part A: For Headquarters personnel, Office of the Chief Human Capital Officer, NRC, Three White Flint North, 11601 Landsdown Street, North Bethesda, Maryland. For Regional personnel, at Regional Offices I–IV listed in Addendum I, Part 2.

Part B: Office of the Chief Human Capital Officer, NRC, Three White Flint North, 11601 Landsdown Street, North Bethesda, Maryland.

NRC has an interagency agreement with the U.S. Department of the Interior (DOI), National Business Center (NBC), in Denver, Colorado, to maintain electronic personnel and payroll information for its employees as of November 2, 2003.

The Office of the Inspector General (OIG) employee files located with the OIG at NRC, 11555 Rockville Pike, Rockville, Maryland.

Duplicate system—Duplicate systems may exist in part, within the organization where the employee actually works, at the locations listed in Addendum I, Parts 1 and 2.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

NRC employees other than the Commissioners, the Inspector General, and temporary personnel employed for less than 1 year.

Part A: Senior Level System employees, GG–1 through GG–15 employees, hourly wage employees, and administratively determined rate employees.

Part B: Senior Executive Service and equivalent employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system contains performance appraisals, which includes performance plans, summary ratings, and other related records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. chapter 43; 42 U.S.C. 2201(d), 5841; and 5 CFR part 293.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In accordance with an interagency agreement the NRC may disclose records to DOI/NBC in order to affect the maintenance of electronic personnel records on behalf of the NRC related to its employees.

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. For agency personnel functions;

b. To disclose information to officials of labor organizations recognized under 5 U.S.C. chapter 71 when relevant and necessary to their duties of exclusive representation concerning personnel policies, practices, and matters affecting working conditions; and

c. For any of the routine uses specified in the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper in folders and on electronic media. Summary ratings from November 2, 2003, forward are stored in the DOI/NBC Federal Personnel/Payroll System. Prior to November 2, 2003 they are maintained at the NRC in the Human Resources Management System (HRMS).

RETRIEVABILITY:

Records are accessed by name and/or social security number.

SAFEGUARDS:

Records are maintained in locking cabinets in a locked room and related documents may be maintained in unlocked file cabinets or an electromechanical file organizer. Automated systems are password protected. Access to and use of these records is limited to those persons whose official duties require such access.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Associate Director for Human Resources Operations and Policy, Office of the Chief Human Capital Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. For OIG employees: Director, Resource Management and Operations Support, Office of the Inspector General, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. For Regional personnel: Regional Personnel Officers at the appropriate Regional Office I–IV listed in Addendum I, Part 2.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Part A: Subject employee and employee's supervisors.

Part B: Subject employee, employee's supervisors, and any documents and sources used to develop critical elements and performance standards for that Senior Executive Service position.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Pursuant to 5 U.S.C. 552a(k)(1) and (k)(5), the Commission has exempted portions of this system of records from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f).

NRC–23

SYSTEM NAME:

Office of Investigations Indices, Files, and Associated Records—NRC.

SYSTEM LOCATION:

Primary system—Office of Investigations, NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

Duplicate system—Records exist within the NRC Regional Office locations, listed in Addendum I, Part 2, during an active investigation.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals and entities referred to in potential or actual investigations and matters of concern to the Office of Investigations and correspondence on matters directed or referred to the Office of Investigations.

CATEGORIES OF RECORDS IN THE SYSTEM:

Office of Investigations correspondence, cases, memoranda, materials including, but not limited to, investigative reports, confidential source information, correspondence to and from the Office of Investigations, memoranda, fiscal data, legal papers, evidence, exhibits, technical data, investigative data, work papers, and management information data.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 2035(c); 42 U.S.C. 2201(c); and 42 U.S.C. 5841; 10 CFR 1.36.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the persons or entities mentioned therein if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To a Federal, State, local, or foreign agency or to an individual or organization if the disclosure is reasonably necessary to elicit information or to obtain the cooperation of a witness or an informant;

b. A record relating to an investigation or matter falling within the purview of the Office of Investigations may be disclosed as a routine use to the referring agency, group, organization, or individual;

c. A record relating to an individual held in custody pending arraignment, trial, or sentence, or after conviction, may be disclosed as a routine use to a Federal, State, local, or foreign prison, probation, parole, or pardon authority, to any agency or individual concerned with the maintenance, transportation, or release of such an individual;

d. A record in the system of records relating to an investigation or matter may be disclosed as a routine use to a foreign country under an international treaty or agreement;

e. To a Federal, State, local, or foreign law enforcement agency to assist in the general crime prevention and detection efforts of the recipient agency or to provide investigative leads to the agency; and

f. A record may be disclosed for any of the routine uses specified in the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Information maintained on paper, photographs, audio/video tapes, and electronic media.

RETRIEVABILITY:

Information retrieved by document text and/or case number.

SAFEGUARDS:

Hard copy files maintained in approved security containers and locking filing cabinets. All records are under visual control during duty hours and are available only to authorized personnel who have a need to know and whose duties require access to the information. The electronic management information system is operated within the NRC's secure LAN/WAN system. Access rights to the system only available to authorized personnel.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Investigations, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORDS ACCESS PROCEDURES:

Same as ''Notification procedure.'' Information classified under Executive Order 12958 will not be disclosed. Information received in confidence will be maintained under the Commission's Policy Statement on Confidentiality, Management Directive 8.8, ''Management of Allegations,'' and the procedures covering confidentiality in Chapter 7 of the Office of Investigations Procedures Manual and will not be disclosed to the extent that disclosure would reveal a confidential source.

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Information is obtained from sources including, but not limited to, NRC officials, employees, and licensees; Federal, State, local, and foreign agencies; and other persons.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Pursuant to 5 U.S.C. 552a(k)(1), (k)(2), and (k)(6), the Commission has exempted portions of this system of records from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f).

NRC–24

SYSTEM NAME:

Property and Supply Records—NRC.

SYSTEM LOCATION:

Property and Labor Services Branch, Directorate for Space Planning and Consolidation, Office of Administration, NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

Duplicate system—Duplicate systems may exist, in part, with designated property custodians at locations listed in Addendum I, Parts 1 and 2.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

NRC employees and contractors who have custody of Government property.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records of NRC sensitive and non-sensitive equipment which includes, but is not limited to, acquisition and depreciated costs, date of acquisition, item description, manufacturer, model number, serial number, stock number, tag number, property custodians, name of individual to whom property is assigned, user id, office affiliation, and office location. Also included are furniture and supply records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; 40 U.S.C. subtitle I, chapter 5.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To maintain an inventory and accountability of Government property;

b. To provide information for clearances of employees who separate from the NRC;

c. To report excess agency property to GSA; and

d. For any of the routine uses specified in paragraph numbers 1, 3, 5, 6, and 7 of the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in automated system. Data entry paper records in file folders.

RETRIEVABILITY:

Records accessed by NRC tag number, name, user id, organization, office location and stock number.

SAFEGUARDS:

Access to and use of these records is limited to those persons whose official duties require such access based on roles and responsibilities. Electronic records are password protected.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html*. Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Property and Labor Services Branch, Directorate for Space Planning and Consolidation, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Information in this system is provided by property custodians, contract specialists, and purchase card holders and/or other individuals buying equipment or supplies on behalf of the NRC.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–25

SYSTEM NAME:

Oral History Program—NRC.

SYSTEM LOCATION:

Office of the Secretary, NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who volunteer to be interviewed for the purpose of providing information for a history of the nuclear regulatory program.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records consist of recorded interviews and transcribed scripts of the interviews.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 2161(b) and 44 U.S.C. 3301.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. For incorporation in publications on the history of the nuclear regulatory program;

b. To provide information to historians and other researchers; and

c. For the routine uses specified in paragraph number 7 of the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained on electronic media.

RETRIEVABILITY:

Information is accessed by the name of the interviewee.

SAFEGUARDS:

Maintained on an access restricted drive. Access to and use of these records is limited to those authorized by the Historian or a designee.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html*. Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

NRC Historian, Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Information in this system of records is obtained from interviews granted on a voluntary basis to the Historian.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–26

SYSTEM NAME:

Transit Subsidy Benefits Program Records—NRC.

SYSTEM LOCATION:

Administrative Services Center, Office of Administration, NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

NRC employees who apply for subsidized mass transit costs.

CATEGORIES OF RECORDS IN THE SYSTEM:

The records consist of an individual's application to participate in the program which includes, but is not limited to, the applicant's name, home address, office telephone number, and information regarding the employee's commuting schedule and mass transit system(s) used.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 7905; 26 U.S.C. 132; 31 U.S.C. 3511; 41 CFR 102–74.210; 41 CFR subtitle F; 41 CFR 102–71.20; Executive Order (E.O.) 9397, as amended by E.O. 13478; E.O. 13150.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To provide statistical reports to the city, county, State, and Federal government agencies;

b. To provide the basis for program approval and issue monthly subsides; and

c. For the routine uses specified in paragraph numbers 1, 4, 5, 6, and 7 in the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper in file folders and on electronic media.

RETRIEVABILITY:

Accessed by name, smart trip card and scanned NRC badge.

SAFEGUARDS:

Paper records are maintained in locked file cabinets under visual control of the Administrative Services Center. Computer files are maintained on a hard drive and accessible by user login. Access to and use of these records is limited to those persons whose official duties require access.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html*. Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Administrative Services Center, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

NRC employees.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–27

SYSTEM NAME:

Radiation Exposure Information and Reporting System (REIRS) Records—NRC.

SYSTEM LOCATION:

Primary system—Oak Ridge Associated Universities (ORAU), Oak Ridge, Tennessee (or current contractor facility).

Duplicate system—Duplicate systems exist, in part, regarding employee exposure records, with the NRC's Radiation Safety Officers at Regional office locations listed in Addendum 1, Part 2, in the Office of Nuclear Reactor Regulations (NRR), the Office of Nuclear Material Safety and Safeguards (NMSS), and the Office of Federal and State Materials and Environmental Management Programs (FSME) at NRC Headquarters, Rockville, Maryland. The Office of Administration (ADM), NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, maintains the employee dosimeter tracking system.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals monitored for radiation exposure while employed by or visiting or temporarily assigned to certain NRC-licensed facilities; individuals who are exposed to radiation or radioactive materials in incidents required to be reported under 10 CFR 20.2201–20.2204 and 20.2206 by all NRC licensees; individuals who may have been exposed to radiation or radioactive materials offsite from a facility, plant installation, or other place of use of licensed materials, or in unrestricted areas, as a result of an incident involving byproduct, source, or special nuclear material.

CATEGORIES OF RECORDS IN THE SYSTEM:

These records contain information relating to an individual's name, sex, social security number, birth date, place and period date of exposure; name and license number of individual's employer; name and number of licensee reporting the information; radiation doses or estimates of exposure received during this period, type of radiation, part(s) or organ(s) exposed, and radionuclide(s) involved.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 7902; 29 U.S.C. 668; 42 U.S.C. 2051, 2073, 2093, 2095, 2111, 2133, 2134, and 2201(o); 10 CFR parts 20 and 34; Executive Order (E.O.) 9397, as amended by E.O. 13478; E.O. 12196, as amended; E.O. 12610.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To provide data to other Federal and State agencies involved in monitoring and/or evaluating radiation exposure received by individuals as enumerated in the paragraph ''Categories of individuals covered by the system;''

b. To return data provided by licensee upon request; and

c. For any of the routine uses specified in the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper and electronic media. The electronic records maintained in Oak Ridge, TN, are in a centralized database management system that is password protected. Backup tapes of the database are generated and maintained at a secure, off site location for disaster recovery purposes. During the processing and data entry, paper records are temporarily stored in designated business offices that are locked when not in use and are accessible only to authorized personnel. Upon completion of data entry and processing, the paper records are stored in an offsite security storage facility accessible only to authorized personnel.

RETRIEVABILITY:

Records are accessed by individual name, social security number, date of birth, and/or by licensee name or number.

SAFEGUARDS:

Information maintained at ORAU is accessible by the Office of Nuclear Regulatory Research (RES) and individuals that have been authorized access by NRC, including all NRC Radiation Safety Officers and ORAU employees that are directly involved in the REIRS project. Reports received and reviewed by the NRC's RES, NRR, NMSS, FSME, and Regional offices are in lockable file cabinets and bookcases in secured buildings. A log is maintained of both telephone and written requests for information.

The data maintained in the REIRS database are protected from unauthorized access by several means. The database server resides in a protected environment with physical security barriers under key-card access control. Accounts authorizing access to the server and databases are maintained by the ORAU REIRS system administrator. In addition, ORAU maintains a computer security ''firewall'' that further restricts access to the ORAU computer network. Authorization for access must be approved by NRC, ORAU project management, and ORAU computer security. Transmittal of data via the Internet is protected by data encryption.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html*. Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

REIRS Project Manager, Radiation Protection Branch, Division of Systems Analysis, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Information in this system of records comes from licensees; the subject individual; the individual's employer; the person in charge of the facility where the individual has been assigned; NRC Form 5, ''Occupational Exposure Record for a Monitoring Period,'' or equivalent, contractor reports, and Radiation Safety Officers.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–28

SYSTEM NAME:

Merit Selection Records—NRC.

SYSTEM LOCATION:

Primary system—Electronic records: NRC has an interagency agreement with the U.S. Department of the Interior (DOI), National Business Center (NBC), in Denver, Colorado, to host the NRC's job application system. Paper records: Headquarters personnel*, Office of Human Resources, NRC, Three White Flint North, 11601 Landsdown Street, North Bethesda, Maryland. Regional personnel, at each of the Regional Offices listed in Addendum I, Part 2. *The Office of the Inspector General (OIG) maintains the paper files for OIG personnel.

Duplicate system—Duplicate systems exist, in part, within the organization with the position vacancy, at the locations listed in Addendum I, Parts 1 and 2.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered by the system include those who have submitted resumes to the NRC, registered in the NRC application system, or applied for Federal employment with the NRC.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system contains application information of persons applying to NRC for Federal employment or merit promotion within the NRC, including application for Federal employment (resumes or similar documents); vacancy announcements; job descriptions; examination results; supervisory evaluation or performance appraisal forms; reference forms; and related correspondence. These records include, but are not limited to, applicant information relating to education, training, employment history, earnings, past performance, awards and commendations, citizenship, veteran's preference, birth date, social security number, and home address and telephone numbers.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 3301, 5101, 7201; 42 U.S.C. chapter 21, subchapter VI; 42 U.S.C. 2201(d); Executive Order (E.O.) 9397, as amended by E.O. 13478; E.O. 11478, as amended; E.O. 12106, as amended.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To prepare reports for a variety of internal and external sources including the Office of Personnel Management, Merit Systems Protection Board; EEOC and EEO Investigators; Union representatives and EEO Committee representatives; and

b. For any of the routine uses specified in the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained in electronic and paper form.

RETRIEVABILITY:

Records are retrieved by vacancy announcement number, applicant name, or social security number.

SAFEGUARDS:

Maintained in a password protected automated system and in lockable file cabinets. Access to and use of these records is limited to those persons whose official duties require such access.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html*. Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Associate Director for Human Resources Operations and Policy, Office of Chief Human Capital Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. For Regional personnel: Regional Personnel Officer at the appropriate Regional Office I–IV listed in Addendum I, Part 2. For applicants to the Honor Law Graduate Program—Honor Law Graduate Program Coordinator, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. For OIG personnel: Personnel Officer, Office of the Inspector General, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.'' Some information was received in confidence and will not be disclosed to the extent that disclosure would reveal a confidential source.

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

The source of this information is the subject individual, or is derived from information supplied by that individual; individual's current and previous supervisors within and outside NRC; pre-employment evaluation data furnished by references and educational institutions whose names were supplied by applicant; and information from other Federal agencies.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Pursuant to 5 U.S.C. 552a(k)(5), the Commission has exempted portions of this system of records from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f).

NRC–29 (Revoked.)
NRC–30 (Revoked.)
NRC–31 (Revoked.)
NRC–32

SYSTEM NAME:

Office of the Chief Financial Officer Financial Transactions and Debt Collection Management Records—NRC.

SYSTEM LOCATION:

Office of the Chief Financial Officer, NRC, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland. NRC has an interagency agreement with the Department of the Interior (DOI), National Business Center (NBC), in Denver, Colorado, as the service provider for the NRC core financial system since May 2002.

Other NRC systems of records contain information that may duplicate some of the records in this system. These other systems include, but are not limited to:

NRC–5, Contracts Records—NRC;

NRC–10, Freedom of Information Act (FOIA) and Privacy Act (PA) Request Records—NRC;

NRC–18, Office of the Inspector General (OIG) Investigative Records—NRC;

NRC–19, Official Personnel Training Records—NRC;

NRC–20, Official Travel Records—NRC;

NRC–21, Payroll Accounting Records—NRC;

NRC–24, Property and Supply Records—NRC; and

NRC–41, Tort Claims and Personal Property Claims Records—NRC.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered are those to whom the NRC owes/owed money, those who receive/received a payment from NRC, and those who owe/owed money to the United States. Individuals receiving payments include, but are not limited to, current and former employees, contractors, consultants, vendors, and others who travel or perform certain services for NRC. Individuals owing money include, but are not limited to, those who have received goods or services from NRC for which there is a charge or fee (NRC licensees, applicants for NRC licenses, Freedom of Information Act requesters, etc.) and those who have been overpaid and owe NRC a refund (current and former employees, contractors, consultants, vendors, etc.).

CATEGORIES OF RECORDS IN THE SYSTEM:

Information in the system includes, but is not limited to, names, addresses, telephone numbers, Social Security Numbers (SSN), Employee Identification Number (EIN), Taxpayer Identification Numbers (TIN), Individual Taxpayer Identification Numbers (ITIN), Data Universal Numbering System (DUNS) number, fee categories, application and license numbers, contract numbers, vendor numbers, amounts owed, background and supporting documentation, correspondence concerning claims and debts, credit reports, and billing and payment histories. The overall agency accounting system contains data and information integrating accounting functions such as general ledger, funds control, travel, accounts receivable, accounts payable, property, and appropriation of funds. Although this system of records contains information on corporations and other business entities, only those records that contain information about individuals that is retrieved by the individual's name or other personal identifier are subject to the Privacy Act.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 552a; 5 U.S.C. 5514; 15 U.S.C. 1681; 26 U.S.C. 6103; 31 U.S.C. chapter 37; 31 U.S.C. 6501–6508; 42 U.S.C. 2201; 42 U.S.C. 5841; 31 CFR 900–904; 10 CFR parts 15, 16, 170, 171; Executive Order (E.O.) 9397, as amended by E.O. 13478; and E.O. 12731.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In accordance with an interagency agreement, the NRC may disclose records to the Deva & Associates as the service provider for the NRC core financial system. In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses or, where determined to be appropriate and necessary, the NRC may authorize Deva & Associates to make the disclosure:

a. To debt collection contractors (31 U.S.C. 3718) or to other Federal agencies such as the Department of the Treasury (Treasury) and DOI for the purpose of collecting and reporting on delinquent debts as authorized by the Debt Collection Act of 1982 or the Debt Collection Improvement Act (DCIA) of 1996;

b. To Treasury; the Defense Manpower Data Center, Department of Defense; the United States Postal Service; government corporations; or any other Federal, State, or local agency to conduct an authorized computer matching program in compliance with the Privacy Act of 1974, as amended, to identify and locate individuals, including Federal employees, who are delinquent in their repayment of certain debts owed to the U.S. Government, including those incurred under certain programs or services administered by the NRC, in order to collect debts under common law or under the provisions of the Debt Collection Act of 1982 or the Debt Collection Improvement Act of 1996 which include by voluntary repayment, administrative or salary offset, and referral to debt collection contractors;

c. To the Department of Justice, United States Attorney, Treasury, Deva & Associates, or other Federal agencies for further collection action on any delinquent account when circumstances warrant;

d. To credit reporting agencies/credit bureaus for the purpose of either adding to a credit history file or obtaining a credit history file or comparable credit information for use in the administration of debt collection. As authorized by the DCIA, NRC may report current (not delinquent) as well as delinquent consumer and commercial debt to these entities in order to aid in the collection of debts, typically by providing an incentive to the person to repay the debt timely;

e. To any Federal agency where the debtor is employed or receiving some form of remuneration for the purpose of enabling that agency to collect a debt owed the Federal Government on NRC's behalf by counseling the debtor for voluntary repayment or by initiating administrative or salary offset procedures, or other authorized debt collection methods under the provisions of the Debt Collection Act of 1982 or the DCIA of 1996. Under the DCIA, NRC may garnish non-Federal wages of certain delinquent debtors so long as required due process procedures are followed. In these instances, NRC's notice to the employer will disclose only the information that may be necessary for the employer to comply with the withholding order;

f. To the Internal Revenue Service (IRS) by computer matching to obtain the mailing address of a taxpayer for the purpose of locating such taxpayer to collect or to compromise a Federal claim by NRC against the taxpayer under 26 U.S.C. 6103(m)(2) and under 31 U.S.C. 3711, 3717, and 3718 or common law. Re-disclosure of a mailing address obtained from the IRS may be made only for debt collection purposes, including to a debt collection agent to facilitate the collection or compromise of a Federal claim under the Debt Collection Act of 1982 or the DCIA of 1996, except that re-disclosure of a mailing address to a reporting agency is for the limited purpose of obtaining a credit report on the particular taxpayer. Any mailing address information obtained from the IRS will not be used or shared for any other NRC purpose or

disclosed by NRC to another Federal, State, or local agency which seeks to locate the same taxpayer for its own debt collection purposes;

g. To refer legally enforceable debts to the IRS or to Treasury's Debt Management Services to be offset against the debtor's tax refunds under the Federal Tax Refund Offset Program;

h. To prepare W–2, 1099, or other forms or electronic submittals, to forward to the IRS and applicable State and local governments for tax reporting purposes. Under the provisions of the DCIA, NRC is permitted to provide Treasury with Form 1099–C information on discharged debts so that Treasury may file the form on NRC's behalf with the IRS. W–2 and 1099 Forms contain information on items to be considered as income to an individual, including certain travel related payments to employees, payments made to persons not treated as employees (*e.g.,* fees to consultants and experts), and amounts written-off as legally or administratively uncollectible, in whole or in part;

i. To banks enrolled in the Treasury Credit Card Network to collect a payment or debt when the individual has given his or her credit card number for this purpose;

j. To another Federal agency that has asked the NRC to effect an administrative offset under common law or under 31 U.S.C. 3716 to help collect a debt owed the United States. Disclosure under this routine use is limited to name, address, SSN, EIN, TIN, ITIN, and other information necessary to identify the individual; information about the money payable to or held for the individual; and other information concerning the administrative offset;

k. To Treasury or other Federal agencies with whom NRC has entered into an agreement establishing the terms and conditions for debt collection cross servicing operations on behalf of the NRC to satisfy, in whole or in part, debts owed to the U.S. Government. Cross servicing includes the possible use of all debt collection tools such as administrative offset, tax refund offset, referral to debt collection contractors, salary offset, administrative wage garnishment, and referral to the Department of Justice. The DCIA requires agencies to transfer to Treasury or Treasury-designated Debt Collection Centers for cross servicing certain nontax debt over 180 days delinquent. Treasury has the authority to act in the Federal Government's best interest to service, collect, compromise, suspend, or terminate collection action under existing laws under which the debts arise;

l. Information on past due, legally enforceable nontax debts more than 180 days delinquent will be referred to Treasury for the purpose of locating the debtor and/or effecting administrative offset against monies payable by the Government to the debtor, or held by the Government for the debtor under the DCIA's mandatory, Government-wide Treasury Offset Program (TOP). Under TOP, Treasury maintains a database of all qualified delinquent nontax debts, and works with agencies to match by computer their payments against the delinquent debtor database in order to divert payments to pay the delinquent debt. Treasury has the authority to waive the computer matching requirement for NRC and other agencies upon written certification that administrative due process notice requirements have been complied with;

m. For debt collection purposes, NRC may publish or otherwise publicly disseminate information regarding the identity of delinquent nontax debtors and the existence of the nontax debts under the provisions of the DCIA of 1996;

n. To the Department of Labor (DOL) and the Department of Health and Human Services (HHS) to conduct an authorized computer matching program in compliance with the Privacy Act of 1974, as amended, to match NRC's debtor records with records of DOL and HHS to obtain names, name controls, names of employers, addresses, dates of birth, and TINs. The DCIA requires all Federal agencies to obtain taxpayer identification numbers from each individual or entity doing business with the agency, including applicants and recipients of licenses, grants, or benefit payments; contractors; and entities and individuals owing fines, fees, or penalties to the agency. NRC will use TINs in collecting and reporting any delinquent amounts resulting from the activity and in making payments;

o. If NRC decides or is required to sell a delinquent nontax debt under 31 U.S.C. 3711(I), information in this system of records may be disclosed to purchasers, potential purchasers, and contractors engaged to assist in the sale or to obtain information necessary for potential purchasers to formulate bids and information necessary for purchasers to pursue collection remedies;

p. If NRC has current and delinquent collateralized nontax debts under 31 U.S.C. 3711(i)(4)(A), certain information in this system of records on its portfolio of loans, notes and guarantees, and other collateralized debts will be reported to Congress based on standards developed by the Office of Management and Budget, in consultation with Treasury;

q. To Treasury in order to request a payment to individuals owed money by the NRC;

r. To the National Archives and Records Administration or to the General Services Administration for records management inspections conducted under 44 U.S.C. 2904 and 2906; and

s. For any of the routine uses specified in the Prefatory Statement of General Routine Uses.

DISCLOSURES TO CONSUMER REPORTING AGENCIES:

Disclosures Pursuant to 5 U.S.C. 552a(b)(12):

Disclosures of information to a consumer reporting agency are not considered a routine use of records. Disclosures may be made from this system to ''consumer reporting agencies'' as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f) (1970)) or the Federal Claims Collection Act of 1966, as amended (31 U.S.C. 3701(a)(3) (1996)).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Information in this system is stored on paper, microfiche, and electronic media.

RETRIEVABILITY:

Automated information can be retrieved by name, SSN, TIN, DUNS number, license or application number, contract or purchase order number, invoice number, voucher number, and/or vendor code. Paper records are retrieved by invoice number.

SAFEGUARDS:

Records in the primary system are maintained in a building where access is controlled by a security guard force. Records are kept in lockable file rooms or at user's workstations in an area where access is controlled by keycard and is limited to NRC and contractor personnel who need the records to perform their official duties. The records are under visual control during duty hours. Access to automated data requires use of proper password and user identification codes by NRC or contractor personnel.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition

Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER:

Controller, Division of the Controller, Office of the Chief Financial Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORDS ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Record source categories include, but are not limited to, individuals covered by the system, their attorneys, or other representatives; NRC; collection agencies or contractors; employing agencies of debtors; and Federal, State and local agencies.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–33

SYSTEM NAME:

Special Inquiry Records—NRC.

SYSTEM LOCATION:

Primary system—Special Inquiry Group, NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

Duplicate system—Duplicate systems exist, in whole or in part, at the locations listed in Addendum I, Parts 1 and 2.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals possessing information regarding or having knowledge of matters of potential or actual concern to the Commission in connection with the investigation of an accident or incident at a nuclear power plant or other nuclear facility, or an incident involving nuclear materials or an allegation regarding the public health and safety related to the NRC's mission responsibilities.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system consists of an alphabetical index file bearing individual names. The index provides access to associated records which are arranged by subject matter, title, or identifying number(s) and/or letter(s). The system incorporates the records of all Commission correspondence, memoranda, audit reports and data, interviews, questionnaires, legal papers, exhibits, investigative reports and data, and other material relating to or developed as a result of the inquiry, study, or investigation of an accident or incident.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 2051, 2052, 2201(c), (i) and (o).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To provide information relating to an item which has been referred to the Commission or Special Inquiry Group for investigation by an agency, group, organization, or individual and may be disclosed as a routine use to notify the referring agency, group, organization, or individual of the status of the matter or of any decision or determination that has been made;

b. To disclose a record as a routine use to a foreign country under an international treaty or convention entered into and ratified by the United States;

c. To provide records relating to the integrity and efficiency of the Commission's operations and management and may be disseminated outside the Commission as part of the Commission's responsibility to inform the Congress and the public about Commission operations; and

d. For any of the routine uses specified in paragraph numbers 1, 2, 4, 5, 6, and 7 of the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper in file folders and electronic media. Documents are maintained in secured vault facilities.

RETRIEVABILITY:

Accessed by name (author or recipient), corporate source, title of document, subject matter, or other identifying document or control number.

SAFEGUARDS:

These records are located in locking filing cabinets or safes in a secured facility and are available only to authorized personnel whose duties require access.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Records Manager, Special Inquiry Group, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.'' Information classified under Executive Order 12958 will not be disclosed. Information received in confidence will not be disclosed to the extent that disclosure would reveal a confidential source.

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

The information in this system of records is obtained from sources including, but not limited to, NRC officials and employees; Federal, State, local, and foreign agencies; NRC licensees; nuclear reactor vendors and architectural engineering firms; other organizations or persons knowledgeable about the incident or activity under investigation; and relevant NRC records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Pursuant to 5 U.S.C. 552a(k)(1), (k)(2), and (k)(5), the Commission has exempted portions of this system of records from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f).

NRC–34 (Revoked.)

NRC–35

SYSTEM NAME:

Drug Testing Program Records—NRC.

SYSTEM LOCATION:

Primary system—Division of Facilities and Security, Office of Administration, NRC, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland.

Duplicate system—Duplicate systems exist in part at the NRC Regional office locations listed in Addendum I, Part 2 (for a temporary period of time); and at the current contractor testing laboratories, collection/evaluation facilities.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

NRC employees, applicants, consultants, licensees, and contractors.

CATEGORIES OF RECORDS IN THE SYSTEM:

These records contain information regarding the drug testing program; requests for and results of initial, confirmatory and follow-up testing, if appropriate; additional information supplied by NRC employees, employment applicants, consultants, licensees, or contractors in challenge to positive test results; and written statements or medical evaluations of attending physicians and/or information regarding prescription or nonprescription drugs.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C 7301; 5 U.S.C. 7361–7363; 42 U.S.C. 2165; 42 U.S.C. 290dd; Executive Order (E.O.) 12564; 9397, as amended by E.O. 13478.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To identify substance abusers within the agency;

b. To initiate counseling and/or rehabilitation programs;

c. To take personnel actions;

d. To take personnel security actions;

e. For statistical reporting purposes. Statistical reporting will not include personally identifiable information; and

f. For the routine uses specified in paragraphs number 6 and 7 of the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper and electronic media. Specimens are maintained in appropriate environments.

RETRIEVABILITY:

Records are indexed and accessed by name, social security number, testing position number, specimen number, drug testing laboratory accession number, or a combination thereof.

SAFEGUARDS:

Records in use are protected to ensure that access is limited to those persons whose official duties require such access. Unattended records are maintained in NRC-controlled space in locked offices, locked desk drawers, or locked file cabinets. Stand-alone and network processing systems are password protected and removable media is stored in locked offices, locked desk drawers, or locked file cabinets when unattended. Network processing systems have roles and responsibilities protection and system security plans. Records at laboratory, collection, and evaluation facilities are stored with appropriate security measures to control and limit access to those persons whose official duties require such access.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Facilities and Security, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

NRC employees, employment applicants, consultants, licensees, and contractors who have been identified for drug testing who have been tested; physicians making statements regarding medical evaluations and/or authorized prescriptions for drugs; NRC contractors for processing including, but not limited to, specimen collection, laboratories for analysis, and medical evaluations; and NRC staff administering the drug testing program to ensure the achievement of a drug-free workplace.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Pursuant to 5 U.S.C. 552a(k)(5), the Commission has exempted portions of this system of records from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f).

NRC–36

SYSTEM NAME:

Employee Locator Records—NRC.

SYSTEM LOCATION:

Primary system—Part 1: For Headquarters personnel: Office of Chief Human Capital Officer, NRC, Three White Flint North, 11601 Landsdown

Street, North Bethesda, Maryland. For Regional personnel: Regional Offices I–IV at the locations listed in Addendum 1, Part 2.

Part 2: Operations Division, Office of Information Services, NRC, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland.

Part 3: Division of Administrative Services, Office of Administration, NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

Duplicate system—Duplicate systems exist, in part, for Incident Response Operations within the Office of Nuclear Security and Incident Response, NRC, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, and at the NRC's Regional Offices, at the locations listed in Addendum I, Part 2.

Duplicate system—Duplicate systems may exist, in part, within the organization where an individual actually works, at the locations listed in Addendum I, Parts 1 and 2.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

NRC employees and contractors.

CATEGORIES OF RECORDS IN THE SYSTEM:

These records include, but are not limited to, an individual's name, home address, office organization and location (building, room number, mail stop), telephone number (home, business, cell and pager), person to be notified in case of emergency (name, address, telephone number), and other related records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

44 U.S.C. 3101, 3301; Executive Order (E.O.) 9397, as amended by E.O. 13478; and E.O. 12656.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To contact the subject individual's designated emergency contact in the case of an emergency;

b. To contact the subject individual regarding matters of official business;

c. To maintain the agency telephone directory (accessible from *www.nrc.gov*);

d. For internal agency mail services; and

e. The routine uses specified in paragraph numbers 6 and 7 of the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic media.

RETRIEVABILITY:

Information is accessed by name.

SAFEGUARDS:

Electronic records are password protected. Access to and use of these records is limited to those persons whose official duties require such access.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Part 1: For Headquarters personnel: Associate Director for Human Resources Operations and Policy, Office of the Chief Human Capital Officer, U.S. Nuclear Regulatory Commission (NRC), Washington, DC 20555–0001; and for Regional personnel: Regional Personnel Officer at the Regional Offices listed in Addendum I, Part 2; Part 2: IT Specialist, Infrastructure Operations Branch, Operations Division, Office of Information Services, NRC, Washington, DC 20555–0001; Part 3: Mail Services Team Leader, Administrative Services Center, Division of Administrative Services, Office of Administration, NRC, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Individual on whom the record is maintained; Employee Express; NRC Form 15, ''Employee Locator Notification'' and other related records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–37

SYSTEM NAME:

Information Security Files and Associated Records—NRC.

SYSTEM LOCATION:

Division of Security Operations, Office of Nuclear Security and Incident Response, NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals include present and former NRC employees, contractors, consultants, licensees, and other cleared persons.

CATEGORIES OF RECORDS IN THE SYSTEM:

These records include information regarding:

a. Personnel who are authorized access to specified levels, categories and types of information, the approving authority, and related documents; and

b. Names of individuals who classify and/or declassify documents (*e.g.,* for the protection of Classified National Security Information and Restricted Data) as well as information identifying the document.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 2161–2169 and 2201(i); Executive Order 13526; 10 CFR part 95.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To prepare statistical reports for the Information Security Oversight Office; and

b. For any of the routine uses specified in the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper in file folders and on electronic media.

RETRIEVABILITY:

Accessed by name and/or assigned number.

SAFEGUARDS:

Information maintained in locked buildings, containers, or security areas under guard and/or alarm protection, as appropriate. Records are processed only on systems approved for processing classified information or accessible through password protected systems for unclassified information. The classified systems are stand-alone systems located within secure facilities or with removable hard drives that are either stored in locked security containers or in alarmed vaults cleared for open storage of TOP SECRET information.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Security Operations, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.'' Some information is classified under Executive Order 13526, and will not be disclosed. Other information has been received in confidence and will not be disclosed to the extent that disclosure would reveal a confidential source.

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

NRC employees, contractors, consultants, and licensees, as well as information furnished by other Government agencies or their contractors.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Pursuant to 5 U.S.C. 552a(k)(1) and (k)(5), the Commission has exempted portions of this system of records from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4), (G), (H), and (I), and (f).

NRC–38

SYSTEM NAME:

Mailing Lists—NRC.

SYSTEM LOCATION:

Primary system—Publications Branch, Division of Administrative Services, Office of Administration, NRC, 11555 Rockville Pike, Rockville, Maryland.

Duplicate system—Duplicate systems exist in whole or in part at the locations listed in Addendum I, Parts 1 and 2.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals, including NRC staff, with an interest in receiving information from the NRC.

CATEGORIES OF RECORDS IN THE SYSTEM:

Mailing lists include an individual's name and address; and title, occupation, and institutional affiliation, when applicable.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

44 U.S.C. 3101, 3301.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. For distribution of documents to persons and organizations listed on the mailing list; and

b. For the routine use specified in paragraph numbers 6 and 7 of the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on electronic media.

RETRIEVABILITY:

Records are accessed by company name, individual name, or file code identification number.

SAFEGUARDS:

Access to and use of these records is limited to those persons whose official duties require such access.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Printing Services Specialist, Publications Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

NRC staff, NRC licensees, and individuals expressing an interest in NRC activities and publications.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–39

SYSTEM NAME:

Personnel Security Files and Associated Records—NRC.

SYSTEM LOCATION:

Division of Facilities and Security, Office of Administration, NRC, Two White Flint North, Rockville, Maryland.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Persons including NRC employees, employment applicants, consultants, contractors, and licensees; other Government agency personnel, other persons who have been considered for an access authorization, special nuclear material access authorization, unescorted access to NRC buildings or nuclear power plants, NRC building access, access to Federal automated information systems or data, or participants in the criminal history program; aliens who visit NRC's facilities; and actual or suspected violators of laws administered by NRC.

CATEGORIES OF RECORDS IN THE SYSTEM:

These records contain information about individuals, which includes, but is not limited to, their name(s), address, date and place of birth, social security number, identifying information, citizenship, residence history, employment history, military history, financial history, foreign travel, foreign contacts, education, spouse/cohabitant and relatives, personal references, organizational membership, medical, fingerprints, criminal record, and security clearance history. These records also contain copies of personnel security investigative reports from other Federal agencies, summaries of investigative reports, results of Federal agency indices and database checks, records necessary for participation in the criminal history program, reports of personnel security interviews, clearance actions information (*e.g.,* grants and terminations), access approval/disapproval actions related to NRC building access or unescorted access to nuclear plants, or access to Federal automated information systems or data, violations of laws, reports of security infraction, and other related personnel security processing documents.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 2011 *et seq.;* 42 U.S.C. 2165, 2201(i), 2201a, and 2284; 42 U.S.C. 5801 *et seq.;* Executive Order (E.O.) 9397, as amended by E.O. 13478; E.O. 10450, as amended; E.O. 10865, as amended; E.O. 13467; E.O. 13526; 10 CFR parts 10, 11, 14, 25, 50, 73, 95; OMB Circular No. A–130, Revised; 5 CFR parts 731, 732, and authorities cited therein.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information in these records may be used by the Division of Facilities and Security and on a need-to-know basis by appropriate NRC officials, Hearing Examiners, Personnel Security Review Panel members, Office of Personnel Management, Central Intelligence Agency, and other Federal agencies:

a. To determine clearance or access authorization eligibility;

b. To determine eligibility for access to NRC buildings or access to Federal automated information systems or data;

c. To certify clearance or access authorization;

d. To maintain the NRC personnel security program;

e. To provide licensees information needed for unescorted access or access to safeguard information determinations; and

f. For any of the routine uses specified in the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records maintained on paper, tapes, and electronic media.

RETRIEVABILITY:

Indexed and accessed by name, social security number, docket number, or a combination thereof.

SAFEGUARDS:

Records in use are protected to ensure that access is limited to those persons whose official duties require such access. Unattended records are maintained in NRC-controlled space in locked offices, locked desk drawers, or locked file cabinets. Mass storage of records is protected when unattended by a combination lock and alarm system. Unattended classified records are protected in appropriate security containers in accordance with Management Directive 12.1.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Facilities and Security, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.'' Some information is classified under Executive Order 12958 and will not be disclosed. Other information has been received in confidence and will not be disclosed to the extent the disclosure would reveal a confidential source.

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

NRC applicants, employees, contractors, consultants, licensees, visitors and others, as well as information furnished by other Government agencies or their contractors.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Pursuant to 5 U.S.C. 552a(k)(1), (k)(2), and (k)(5), the Commission has exempted portions of this system of records from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f).

NRC–40

SYSTEM NAME:

Facility Security Access Control Records—NRC.

SYSTEM LOCATION:

Primary system—Division of Facilities and Security, Office of Administration, NRC, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland.

Duplicate system—Duplicate systems exist in part at NRC Regional Offices and the NRC Technical Training Center at the locations listed in Addendum I, Part 2.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former NRC employees, consultants, contractors, other Government agency personnel, and approved visitors.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system includes information regarding: (1) NRC personal identification badges issued for continued access to NRC-controlled space; and (2) records regarding visitors to NRC. The records include, but are not limited to, an individual's name, social security number, electronic image, badge number, citizenship, employer, purpose of visit, person visited, date and time of visit, and other information contained on Government issued credentials.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 2165–2169 and 2201; Executive Order (E.O.) 9397, as amended by E.O. 13478; E.O. 13462, as amended by E.O. 13516.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To control access to NRC classified information and to NRC spaces by human or electronic means;

b. Information (identification badge) may also be used for tracking applications within the NRC for other than security access purposes;

c. The electronic image used for the NRC employee personal identification badge may be used for other than security purposes only with the written consent of the subject individual; and

d. For any of the routine uses specified in the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper and electronic media.

RETRIEVABILITY:

Information is indexed and accessed by individual's name, social security number, identification badge number, employer's name, date of visit, or sponsor's name.

SAFEGUARDS:

All records are maintained in NRC-controlled space that is secured after normal duty hours or a security area under guard presence in a locked security container/vault. There is an approved security plan which identifies the physical protective measures and access controls (*i.e.,* passwords and software design limiting access based on each individual's role and responsibilities relative to the system) specific to each system.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Facilities and Security, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Sources of information include NRC employees, contractors, consultants, employees of other Government agencies, and visitors.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–41

SYSTEM NAME:

Tort Claims and Personal Property Claims Records—NRC.

SYSTEM LOCATION:

Primary system—Office of the General Counsel, NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

Duplicate system—Duplicate systems exist, in whole or in part, in the Office of the Chief Financial Officer, NRC, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, and at the locations listed in Addendum I, Parts 1 and 2. Other NRC systems of records, including but not limited to, NRC–18, ''Office of the Inspector General (OIG) Investigative Records—NRC and Defense Nuclear Facilities Safety Board (DNFSB), '' and NRC–32, ''Office of the Chief Financial Officer Financial Transactions and Debt Collection Management Records—NRC,'' may contain some of the information in this system of records.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have filed claims with NRC under the Federal Tort Claims Act or the Military Personnel and Civilian Employees' Claims Act and individuals who have matters pending before the NRC that may result in a claim being filed.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system contains information relating to loss or damage to property and/or personal injury or death in which the U.S. Government may be liable. This information includes, but is not limited to, the individual's name, home address and phone number, work address and phone number, driver's license number, claim forms and supporting documentation, police reports, witness statements, medical records, insurance information, investigative reports, repair/replacement receipts and estimates, litigation documents, court decisions, and other information necessary for the evaluation and settlement of claims and pre-claims.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Federal Tort Claims Act, 28 U.S.C. 2671 *et seq.;* Military Personnel and Civilian Employees' Claims Act, 31 U.S.C. 3721; 44 U.S.C. 3101.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, NRC may disclose

information contained in a record in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To third parties, including claimants' attorneys, insurance companies, witnesses, potential witnesses, local police authorities where an accident occurs, and others who may have knowledge of the matter to the extent necessary to obtain information that will be used to evaluate, settle, refer, pay, and/or adjudicate claims;

b. To the Department of Justice (DOJ) when the matter comes within their jurisdiction, such as to coordinate litigation or when NRC's authority is limited and DOJ advice or approval is required before NRC can award, adjust, compromise, or settle certain claims;

c. To the appropriate Federal agency or agencies when a claim has been incorrectly filed with NRC or when more than one agency is involved and NRC makes agreements with the other agencies as to which one will investigate the claim;

d. The Department of the Treasury to request payment of an award, compromise, or settlement of a claim;

e. Information contained in litigation records is public to the extent that the documents have been filed in a court or public administrative proceeding, unless the court or other adjudicative body has ordered otherwise. This public information, including information concerning the nature, status, and disposition of the proceeding, may be disclosed to any person, unless it is determined that release of specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy;

f. To the National Archives and Records Administration or to the General Services Administration for records management inspections conducted under 44 U.S.C. 2904 and 2906; and

g. For any of the routine uses specified in the Prefatory Statement of General Routine Uses.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosure Pursuant to 5 U.S.C. 552a(b)(12):

Disclosure of information to a consumer reporting agency is not considered a routine use of records. Disclosures may be made from this system of records to ''consumer reporting agencies'' as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f) (1970)) or the Federal Claims Collection Act of 1966, as amended (31 U.S.C. 3701(a)(3) (1996)).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Information in this system of records is stored on paper and computer media.

RETRIEVABILITY:

Information is indexed and accessed by the claimant's name and/or claim number.

SAFEGUARDS:

The paper records and log books are stored in locked file cabinets or locked file rooms and access is restricted to those agency personnel whose official duties and responsibilities require access. Automated records are protected by password.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER:

Assistant General Counsel for Administration, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Information is obtained from a number of sources, including but not limited to, claimants, NRC employees involved in the incident, witnesses or others having knowledge of the matter, police reports, medical reports, investigative reports, insurance companies, and attorneys.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–42

SYSTEM NAME:

Strategic Workforce Planning Records—NRC.

SYSTEM LOCATION:

Primary system—Technical Training Center, NRC, 5746 Marlin Road, Suite 200, Chattanooga, Tennessee.

Duplicate system—Duplicate systems may exist, in part, at the locations listed in Addendum I, Parts 1 and 2.

CATEGORIES OF INDIVIDUALS COVERED:

Current, prospective, and former NRC employees, experts, and consultants.

CATEGORIES OF RECORDS IN THE SYSTEM:

Specific information maintained on individuals includes individual skills assessments that identify the knowledge and skills possessed by the individual and the levels of skill possessed, and may include a skills profile containing, but not limited to, their name; service computation date; series and grade; work and skills experience; special qualifications; licenses and certificates held; and availability for geographic relocation.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 3396; 5 U.S.C. 4103; 42 U.S.C. 2201; 44 U.S.C. 3506; Executive Order (E.O.) 9397, as amended by E.O. 13478; E.O. 11348, as amended by E.O. 12107.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The primary use of the records will be to assess the knowledge and skills needed to perform the functions assigned to individuals and their organizations.

Information in the system may be used by the NRC to assess the skills of the staff to develop an organizational training plan/program; to prepare individual training plans; to develop recruitment plans; and to assign personnel. Other offices may maintain similar kinds of records relative to their specific duties, functions, and responsibilities.

In addition to the disclosures permitted under subsection (b) of the

Privacy Act, which includes disclosure to other NRC employees who have a need for the information in the performance of their duties, NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the information was collected under the following routine uses:

a. To employees and contractors of other Federal, State, local, and foreign agencies or to private entities in connection with joint projects, working groups, or other cooperative efforts in which the NRC is participating;

b. To the National Archives and Records Administration or to the General Services Administration for records management inspections conducted under 44 U.S.C. 2904 and 2906; and

c. For any of the routine uses specified in the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSITION OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on electronic media.

RETRIEVABILITY:

Information may be retrieved by, but not limited to, the individual's name; office; skill level; various skills; or work experience.

SAFEGUARDS:

Records are maintained in areas where access is controlled by keycard and is limited to NRC and contractor personnel. Access to computerized records requires use of password and user identification codes. Level of access is determined by roles and responsibilities.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER AND ADDRESS:

Chief, Program Management, Human Capital Analysis Branch, Office of the Chief Human Capital Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Information is obtained from a number of sources, including but not limited to, the individual to whom it pertains, system of records NRC–11, supervisors and other NRC officials, contractors, and other agencies or entities.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–43

SYSTEM NAME:

Employee Health Center Records—NRC.

SYSTEM LOCATION:

Primary system—Employee Health Center, NRC, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

Duplicate system—Duplicate systems exist, in part, at health care facilities operating under a contract or agreement with NRC for health-related services in the vicinity of each of NRC's Regional offices listed in Addendum I, Part 2. NRC's Regional offices may also maintain copies of occupational health records for their employees.

This system may contain some of the information maintained in other systems of records, including NRC–11, ''General Personnel Records (Official Personnel Folder and Related Records)—NRC,'' NRC–17, ''Occupational Injury and Illness Records—NRC,'' and NRC–44, ''Employee Fitness Center Records—NRC.''

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former NRC employees, consultants, contractors, other Government personnel, and anyone on NRC premises who requires emergency or first-aid treatment.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system is comprised of records developed as a result of voluntary employee use of health services provided by the Health Center, and of emergency health services rendered by Health Center staff to individuals for injuries and illnesses suffered while on NRC premises. Specific information maintained on individuals may include, but is not limited to, their name, date of birth, and social security number; medical history and other biographical data; test reports and medical diagnoses based on employee health maintenance physical examinations or health screening programs (tests for single medical conditions or diseases); history of complaint, diagnosis, and treatment of injuries and illness rendered by the Health Center staff; immunization records; records of administration by Health Center staff of medications prescribed by personal physicians; medical consultation records; statistical records; daily log of patients; and medical documentation such as personal physician correspondence, test results submitted to the Health Center staff by the employee; and occupational health records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 7901; Executive Order 9397, as amended by E.O. 13478.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To refer information required by applicable law to be disclosed to a Federal, State, or local public health service agency concerning individuals who have contracted certain communicable diseases or conditions in an effort to prevent further outbreak of the disease or condition;

b. To disclose information to the appropriate Federal, State, or local agency responsible for investigation of an accident, disease, medical condition, or injury as required by pertinent legal authority;

c. To disclose information to the Office of Workers' Compensation Programs in connection with a claim for benefits filed by an employee;

d. To Health Center staff and medical personnel under a contract or agreement with NRC who need the information in order to schedule, conduct, evaluate, or follow up on physical examinations, tests, emergency treatments, or other medical and health care services;

e. To refer information to private physicians designated by the individual when requested in writing;

f. To the National Archives and Records Administration or to the General Services Administration for records management inspections conducted under 44 U.S.C. 2904 and 2906; and

g. For any of the routine uses specified in the Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders, on electronic media, and on file cards, logs, x-rays, and other medical reports and forms.

RETRIEVABILITY:

Records are retrieved by the individual's name, date of birth, and social security number, or any combination of those identifiers.

SAFEGUARDS:

Records in the primary system are maintained in a building where access is controlled by a security guard force and entry to each floor is controlled by keycard. Records in the system are maintained in lockable file cabinets with access limited to agency or contractor personnel whose duties require access. The records are under visual control during duty hours. Access to automated data requires use of proper password and user identification codes by authorized personnel.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESSES:

Technical Assistance Project Manager, Office of the Chief Human Capital Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9; and provide their full name, any former name(s), date of birth, and Social Security number.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure''

RECORD SOURCE CATEGORIES:

Information in this system of records is obtained from a number of sources including, but not limited to, the individual to whom it pertains; laboratory reports and test results; NRC Health Center physicians, nurses, and other medical technicians or personnel who have examined, tested, or treated the individual; the individual's coworkers or supervisors; other systems of records; the individual's personal physician(s); NRC Fitness Center staff; other Federal agencies; and other Federal employee health units.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–44

SYSTEM NAME:

Employee Fitness Center Records—NRC.

SYSTEM LOCATION:

Primary system—Fitness Center, NRC, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland.

Duplicate system—Regional offices, listed in Addendum I, Part 2, only maintain lists of their employees who receive subsidy from NRC for off-site fitness center memberships.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

NRC employees who apply for membership at the Fitness Center, including current and former members.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system includes applications to participate in NRC's Fitness Center, information on an individual's degree of physical fitness and their fitness activities and goals; and various forms, memoranda, and correspondence related to Fitness Facilities membership and financial/payment matters. Specific information contained in the application for membership includes the employee applicant's name, gender, age, badge id, height, weight, and medical information, including a history of certain medical conditions; the name of the individual's personal physician and any prescription or over-the-counter drugs taken on a regular basis; and the name and address of a person to be notified in case of emergency.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 7901; Executive Order (E.O.) 9397, as amended by E.O. 13478.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To the individual listed as an emergency contact, in the event of an emergency;

b. To the National Archives and Records Administration or to the General Services Administration for records management inspections conducted under 44 U.S.C. 2904 or 2906; and

c. For any of the routine uses specified in the Prefatory Statement of General Routine Uses.

DISCLOSURES TO CONSUMER REPORTING AGENCIES:

Disclosures Pursuant to 5 U.S.C. 552a(b)(12):

Disclosures of information to a consumer reporting agency are not considered a routine use of records. Disclosures may be made from this system to ''consumer reporting agencies'' as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f) (1970)) or the Federal Claims Collection Act of 1966, as amended (31 U.S.C. 3701(a)(3) (1996)).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on paper and electronic media.

RETRIEVABILITY:

Information is indexed and accessed by an individual's name and/or NRC Badge ID number.

SAFEGUARDS:

Records are maintained in a building where access is controlled by a security guard force. Access to the Fitness Center is controlled by keycard and bar code verification. Records in paper form are stored alphabetically by individuals' names in lockable file cabinets maintained in the NRC where access to the records is limited to agency and Fitness Center personnel whose duties require access. The records are under visual control during duty hours. Automated records are protected by screen saver. Access to automated data requires use of proper password and user identification codes. Only authorized personnel have access to areas in which information is stored.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Employee Assistance Program Manager, Office of the Chief Human Capital Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

Information in this system of records is principally obtained from the subject individual. Other sources of information include, but are not limited to, the NRC Fitness Center Director, staff physicians retained by the NRC, and the individual's personal physicians.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

NRC–45

SYSTEM NAME:

Electronic Credentials for Personal Identity Verification–NRC.

SYSTEM LOCATION:

Primary system—Office of Information Services, NRC, White Flint North Complex, 11555 Rockville Pike, Rockville, Maryland, and current contractor facility.

Duplicate system–Duplicate systems may exist, in whole or in part, at the locations listed in Addendum I, Part 2.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered are persons who have applied for the issuance of electronic credentials for signature, encryption, and/or authentication purposes; have had their credentials renewed, replaced, suspended, revoked, or denied; have used their credentials to electronically make contact with, retrieve information from, or submit information to an automated information system; or have corresponded with NRC or its contractor concerning digital services.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system contains information needed to establish and verify the identity of users, to maintain the system, and to establish accountability and audit controls. System records may include: (a) Applications for the issuance, amendment, renewal, replacement, or revocation of electronic credentials, including evidence provided by applicants or proof of identity and authority, and sources used to verify an applicant's identity and authority; (b) credentials issued; (c) credentials denied, suspended, or revoked, including reasons for denial, suspension, or revocation; (d) a list of currently valid credentials; (e) a list of currently invalid credentials; (f) a record of validation transactions attempted with electronic credentials; and (g) a record of validation transactions completed with electronic credentials.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; 42 U.S.C. 2165 and 2201(i); 44 U.S.C. 3501, 3504; Electronic Government Act of 2002, 44 U.S.C. chapter 36; Homeland Security Presidential Directive 12 (HSPD–12), Policy for a Common Identification Standard for Federal Employees and Contractors, August 27, 2004; Executive Order (E.O.) 9397, as amended by E.O. 13478.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the NRC may disclose information contained in this system of records without the consent of the subject individual if the disclosure is compatible with the purpose for which the record was collected under the following routine uses:

a. To agency electronic credential program contractors to compile and maintain documentation on applicants for verifying applicants' identity and authority to access information system applications; to establish and maintain documentation on information sources for verifying applicants' identities; to ensure proper management, data accuracy, and evaluation of the system;

b. To Federal authorities to determine the validity of subscriber digital certificates and other identity attributes;

c. To the National Archives and Records Administration (NARA) for records management purposes;

d. To a public data repository (*only name, email address, organization, and public key*) to facilitate secure communications using digital certificates; and

e. Any of the routine uses specified in the Prefatory Statement of General Routine Uses.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosure of system records to consumer reporting systems is not permitted.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored electronically or on paper.

RETRIEVABILITY:

Records are retrievable by an individual's name, email address, certificate status, certificate number or credential number, certificate issuance date, or approval role.

SAFEGUARDS:

Technical, administrative, and personnel security measures are

implemented to ensure confidentiality, integrity, and availability of the system data stored, processed, and transmitted. Hard copy documents are maintained in locking file cabinets. Electronic records are, at a minimum, password protected. Access to and use of these records is limited to those individuals whose official duties require access.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the National Archives and Records Administration (NARA) approved disposition schedules which can be found in the NRC Comprehensive Records Disposition Schedule, NUREG–0910, the NARA General Records Schedules, as well as in recently approved Requests for Records Disposition Authorities. NRC records disposition schedules are accessible through the NRC's Web site at *http://www.nrc.gov/reading-rm/records-mgmt.html.* Records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Operations Division, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act and Privacy Act Officer, Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and comply with the procedures contained in NRC's Privacy Act regulations, 10 CFR part 9.

RECORD ACCESS PROCEDURE:

Same as ''Notification procedure.''

CONTESTING RECORD PROCEDURE:

Same as ''Notification procedure.''

RECORD SOURCE CATEGORIES:

The sources for information are the individuals who apply for digital certificates, the NRC and contractors using multiple sources to verify identities, and internal system transactions designed to gather and maintain data needed to manage and evaluate the digital certificate program.

EXEMPTIONS CLAIMS FOR THE SYSTEM:

None.

Addendum I—List of U.S. Nuclear Regulatory Commission Locations

Part 1—NRC Headquarters Offices

1. One White Flint North, 11555 Rockville Pike, Rockville, Maryland.
2. Two White Flint North, 11545 Rockville Pike, Rockville, Maryland.
3. Three White Flint North, 11601 Landsdown Street, North Bethesda, Maryland.
4. Church Street Building, 21 Church Street, Rockville, Maryland.

Part 2—NRC Regional Offices

1. NRC Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, Pennsylvania.
2. NRC Region II, Marquis One Tower, 245 Peachtree Center Avenue NE., Suite 1200, Atlanta, Georgia.
3. NRC Region III, 2443 Warrenville Road, Suite 210, Lisle, Illinois.
4. NRC Region IV, 1600 East Lamar Boulevard, Arlington, Texas.
5. NRC Technical Training Center, Osborne Office Center, 5746 Marlin Road, Suite 200, Chattanooga, Tennessee.

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